

**Impacting Shop Floor Behavior in the Context of Pharmaceutical Operational
Excellence Programs - A Management Control Perspective**

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The President:

Prof. Dr. Bernhard Ehrenzeller

Danksagung

Diese Dissertation entstand im Rahmen meiner Tätigkeit als wissenschaftlicher Mitarbeiter im Bereich Produktionsmanagement am Institut für Technologiemanagement der Universität St.Gallen (ITEM-HSG). Zwischen 2016 und 2020 konnte ich bei der Bearbeitung von dissertationsbezogenen Industrie- und Forschungsprojekten Einblicke in das Produktionsmanagement von führenden Unternehmen der pharmazeutischen Industrie gewinnen, welche die Grundlage für diese Arbeit bilden.

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Summary

The management of shop floor behavior plays a critical role for the success of operational improvement programs, which rely on the workers that perform the direct value creation tasks. But what precisely should managers do to influence that behavior constructively? In the corresponding stream of Operational Excellence (OPEX) literature, this question has recently experienced an increase in research interest.

For pharmaceutical manufacturers, addressing this question can be considered mission critical for two main reasons. First, OPEX programs are viewed as an antidote for low quality levels in pharmaceutical manufacturing, which are significantly lower compared to other industries. Second, procedural regulation can affect what behaviors are deemed acceptable. This should be accounted for, as OPEX and regulatory compliance can have differing behavioral priorities.

The purpose of this dissertation is to provide theoretical and practical guidance for impacting shop floor behavior with pharmaceutical OPEX programs to facilitate balanced and high levels of operational performance. For this purpose, this research draws on literature on OPEX, Management Control (MC) and structuration theory to develop a research model in a first step. A mixed-method approach combining qualitative analysis and quantitative hierarchical linear regression analysis is then applied to empirically study the determinants of shop floor behavior in the context of pharmaceutical OPEX programs.

The research findings suggest that the interplay between structural and behavioral determinants of shop floor behavior can lead to unintended consequences that are context dependent. They further suggest that this interplay is not comprehensively accounted for as part of pharmaceutical OPEX programs, since the underlying determinants are typically managed in isolation. Finally, the regression results underline the importance of taking unintended consequences that result from said interplay seriously, suggesting that MC has significant positive and negative moderation effects, which can increase respectively decrease the performance returns from OPEX programs.

Zusammenfassung

Das Management des Mitarbeiterverhaltens im Produktionsbereich spielt eine zentrale Rolle für den Erfolg von operativen Verbesserungsprogrammen, die auf der Einbindung der direkt wertschöpfenden Mitarbeiter beruhen. Doch was genau können Manager tun, um dieses Verhalten in konstruktiver Weise zu beeinflussen? Diese Frage hat kürzlich ein steigendes Forschungsinteresse in der entsprechenden Operational Excellence (OPEX) Literatur erfahren.

Für Pharmaunternehmen ist die Beantwortung dieser Frage aus zwei Hauptgründen erfolgsentscheidend. Ersten werden OPEX Programme als Allheilmittel gegen niedrige Qualitätsniveaus in der pharmazeutischen Produktion angesehen, welches verglichen mit anderen Branchen deutlich niedriger ist. Zweitens können regulatorische Verfahrensvorschriften einen Einfluss darauf haben, welche Verhaltensweisen als akzeptabel gelten. Dies sollte berücksichtigt werden, da OPEX und regulatorische Vorschriften unterschiedliche Prioritäten bezüglich Mitarbeiterverhalten haben können.

Das Ziel dieser Dissertation ist es, eine theoretische und praktische Hilfestellung zur Beeinflussung des Mitarbeiterverhaltens im Kontext pharmazeutischer OPEX Programme zu geben für eine ausgewogene und hohe operative Leistungsfähigkeit. Dazu stützt sich diese Arbeit auf die Literatur aus den Bereichen OPEX, Management Control (MC) und Strukturierungstheorie, um zunächst ein Forschungsmodell zu entwickeln. Anschliessend wird ein Forschungsansatz verfolgt, der qualitative Analyse Methoden mit einer quantitativen linearen hierarchischen Regressionsanalyse kombiniert, um empirisch relevante Verhaltens-Determinanten zu untersuchen.

Die Forschungsergebnisse legen nahe, dass das Zusammenspiel zwischen strukturellen und verhaltensbezogenen Determinanten des Mitarbeiterverhaltens im Produktionsbereich zu unbeabsichtigten, kontextabhängigen Konsequenzen führen kann. Ferner legen sie nahe, dass dieses Zusammenspiel nicht ausreichend im Rahmen von pharmazeutischen OPEX-Programmen berücksichtigt wird, da die zugrundeliegenden Determinanten typischerweise isoliert behandelt werden. Abschliessend unterstreichen die Regressionsergebnisse die Bedeutung von unbeabsichtigten MC-Konsequenzen, die sich aus diesem Zusammenspiel ergeben. Sie legen nahe, dass MC sowohl signifikante positive und negative Moderationseffekte haben kann und somit den Beitrag von OPEX-Programmen zur operativen Verbesserung erhöhen oder verringern können.

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List of Abbreviations

AVE	Average Variance Extracted
BM	Benchmarking
CFI	Comparative Fit Index
CAPA	Corrective and Preventive Actions
cf.	confer
CFA	Confirmatory Factor Analysis
cGMP	Current Good Manufacturing Practice
CI	Continuous improvement
CMO	Contract Manufacturing Organization
CR	Composite Variability
EE	Employee Empowerment (measurement instrument)
e.g.	exempli gratia
EMA	European Medicine Agency
EMS	Effective Management System
FDA	U.S. Food and Drug Administration
GMP	Good Manufacturing Practice
GS	Goal Setting (measurement instrument)
ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ITEM-HSG	Institute of Technology Management at the University of St.Gallen
JIT	Just-in-time production
KPI	Key Performance Indicator
LP	Lean Production
LPS	Lean Production System
MC	Management Control
MB	Management Behavior
MRQ	Main Research Question

MSW	Management Standard Work
OPEX	Operational Excellence
PCA	Principal Component Analysis
PM	Performance measurement (measurement instrument)
PMDA	Pharmaceuticals and Medical Devices Agency
QM	Quality management
RMSEA	Root Mean Square Error of Approximation
SRQ	Sub Research Question
STD	Standardized Work (measurement instrument)
TPM	Total productive maintenance
TPS	Toyota production system
TQC	Total Quality Control
TQM	Total quality management
TR	Training (measurement instrument)
UB	Unintended Behavior
UME	Unintended Management Control Effect
VIS	Visualization (measurement instrument)
WCM	World class manufacturing

1 Introduction

‘Excellence is what one routinely does’ or ‘excellence is a philosophy’. These are widely accepted mantras in the existing literature on corporate operational improvement programs. In production, excellence further assumes sophisticated technical operations and, at times, the use of state-of-the-art technology. Yet, only seldom, it is associated with management structures that are adequate for impacting organizational behavior for the task at hand. However, research on social science suggests that integrating such perspective could make a valuable contribution to understanding why improvement initiatives succeed or fail.

Dynamics and increasing competition in global markets urge firms to improve their operations continuously. In response, many manufacturers have launched holistic and company-specific Operational Excellence (OPEX) programs (Netland, 2013), which can be viewed as strategic initiatives intended to gain respectively to sustain competitive advantage based on continuous operational improvement.

Despite widespread popularity of OPEX programs (Bhamu & Sangwan, 2014), and various scientific studies confirming their positive effects on firm performance (van der Steen & Tillema, 2018), many modern organizations still fail to successfully implement these (Bortolotti, Boscari et al., 2015; Losonci et al., 2017). This includes pharmaceutical manufactures, who have embarked on the OPEX journey relatively late compared to other industries (Friedli et al., 2013; Garza-Reyes et al., 2018).

To understand why OPEX programs fail, researchers have highlighted the need for adopting socio-technical perspectives to study the effects from implementing OPEX programs comprehensively (Bortolotti, Boscari et al., 2015). OPEX programs can be conceptualized as sets of organizational practices, which work synergistically to improve the processes of value creation (Shah & Ward, 2003). From a socio-technical perspective, these practices can further be classified as either operations-oriented or people-oriented (Bortolotti, Boscari et al., 2015; Camuffo & Gerli, 2018; Hadid & Mansouri, 2014). They can be viewed as highly interrelated practices that jointly impact the effectiveness of OPEX programs (Shah & Ward, 2007).

In line with the socio-technical perspective, existing literature recognizes that the effectiveness of OPEX programs is highly dependent on the behavior of employees on the shop floor (Losonci et al., 2017), as it can affect process execution and thus the outcome of operations. Hence, due to the potential of OPEX programs to increase operational performance, the ability to effectively guide such behavior could help

manufacturers, including producers of pharmaceutical products, better cope with the demands of today's competitive landscape.

1.1 Research Problem

Like manufacturing companies from other industries, pharmaceutical firms are facing a business need to implement OPEX programs. Among others, the industry faces an increasing number of manufacturing related product issues. These include product recalls and drug shortages, which affect patient safety and ultimately impact business results (Yu & Kopcha, 2017).

Almost two thirds of all drug shortages are due to issues of operational quality, including quality manufacturing issues and delays (FDA, 2019b). In addition, pharmaceutical manufacturers currently only achieve two to three sigma quality levels, which is significantly lower compared to other industries, which achieve in parts six sigma levels¹. In the face of these quality issues, regulators encourage pharmaceutical companies to implement holistic improvement programs for the purpose of controlling and enhancing the quality of their manufacturing operations (FDA, 2016). In addition, scholars specifically identify OPEX programs as a potential antidote for low quality in pharmaceutical manufacturing, which can facilitate and sustain high levels of quality in the pharmaceutical operations (Yu & Kopcha, 2017).

In addition to improving quality performance, pharmaceutical companies also need to enhance their operations more broadly. On the one hand, they face increasing market pressure to reduce the cost of production and to reduce production lead time. Despite still relatively large profit margins compared to other industries, increasing R&D costs, expiring patents and declining production efficiencies resulted in a considerable drop in profits (Nenni et al., 2014). On the other hand, regulators push for more balanced operational improvement. One of the most influential global regulatory agencies, the U.S. Food and Drug Administration (FDA), has formulated its vision for pharmaceutical manufacturing in the twenty-first century as “a maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drugs without extensive regulatory oversight” (FDA, 2004). For the reasons outlined above, pharmaceutical manufacturers therefore have a business need to improve operational performance holistically and in terms of both effectiveness and efficiency.

¹ Two sigma quality levels correspond to 308.538 defects per one million opportunities, compared to six sigma levels, which correspond to 3.4 defects per one million opportunities.

Despite the outlined opportunities from adopting OPEX programs, pharmaceutical manufacturers have tapped only some of its potential. Among others, they started their OPEX journey only in the early 2000s and thus relatively late compared to other industries. Prior to that, improvement efforts were predominantly focused on product quality assurance to the neglect of other operational performance dimensions such as cost performance or process timeliness (Friedli et al., 2013). The understanding of how to successfully implement and sustain OPEX is therefore still limited, since the OPEX transformation of the pharmaceutical industry is still in its early stages.

In addition, while existing excellence frameworks theoretically solved the problem of separating quality programs from holistic OPEX programs, this message has not yet been translated into the day-to-day operations of pharmaceutical manufacturers, as (Friedli et al., 2018) point out. In practice, quality improvement efforts therefore still take place separate from other improvement activities as part of OPEX programs.

Finally, procedural regulation can affect what behaviors are deemed acceptable in pharmaceutical manufacturing. This should be accounted for, as OPEX and regulatory compliance can have differing behavioral priorities. The behavioral priorities of OPEX include involved employees, reduction of waste, continuous improvement, as well as balanced operational performance (Friedli et al., 2013). Compliance-related priorities, on the other hand, include achieving and maintaining a state of control, change control, quality focus and following standard procedures (ICH, 2008). (Friedli et al., 2018) illustrate the differences in the two approaches by pointing out that following standard operating procedures (SOPs) can “to some degree, ensure a certain level of quality in cases where the behavior is not yet on a level that everybody thinks in Quality and strives for continuous improvement. After years of having researched Operational Excellence, we know that the only way to truly embed excellence in an organization is to instill it in every single employee.” (p. 277). Against this backdrop, satisfying both behavioral priorities it is therefore a non-trivial task in the regulated pharmaceutical manufacturing environment.

Based on the identified need to implement OPEX programs, and in the light of the recognized importance of shop floor behavior (SFB) for their success, managers of pharmaceutical manufacturers look for effective means that they can apply to influence SFB in desired ways. Meanwhile, research on human behavior management for OPEX is still limited, in terms of both the means that managers can apply, as well as their performance effects. As a result, managers have a limited understanding how the means that they apply to direct behavior as part of OPEX programs influence its overall effectiveness in the pharmaceutical manufacturing environment.

On the one hand, researchers shifted their focus only recently towards empirically studying the management of organizational behavior for OPEX, despite the recognized need to involve all organizational members in the process of continuous operational improvement. Notable studies that empirically investigate the role of human behavior management as part of OPEX programs include (Cadden et al., 2020), who focus on the role of cultural practices for OPEX implementation. (Camuffo & Gerli, 2018) study the effect of management behavior (MB) for OPEX. (Galeazzo et al., 2017) and (Knol et al., 2019) investigate the role of improvement routines in OPEX programs and the organizational infrastructure of continuous improvement. (Tortorella et al., 2018) study the influence that leadership styles have on OPEX adoption.

On the other hand, empirical research that investigates the effects of the means that managers apply to direct behavior, including their performance effects, is still limited to few studies. Existing literature is highly skewed towards the study of either technical or people-oriented practices. In contrast, only a few studies distinguish people-oriented from operations-oriented practices in OPEX programs to holistically investigate their interplay as well as their separate performance effects. Consequently, there is little consensus about what OPEX practices constitute people-oriented practices respectively operations-oriented practices to begin with. Furthermore, empirical research on the effectiveness of people-oriented OPEX practices is limited and largely qualitative. As a result, managers rely on broad and sometimes ambiguous principles to design, implement and sustain OPEX programs, without further guidance what practices contribute to effectiveness and sustainment of OPEX programs. Consequentially, their ability to support respective practices by acting in adequate ways is limited.

In conclusion, despite the recognized importance of the management for human behavior management for OPEX implementation, existing research lacks practical and theoretical guidance for directing organizational behavior in supportive ways. Particularly, empirical knowledge on effective people-oriented OPEX practices for impacting the behavior of the essential shop floor personnel is still inadequate, despite their recognized interrelatedness with operations-oriented OPEX practices. To date, managers including those from pharmaceutical firms, can therefore draw on only limited guidance how to apply people-oriented OPEX practices to influence SFB in ways that support an effective implementation of OPEX programs.

1.2 Terms and Definitions

Operational Excellence: Following (Friedli et al., 2013), OPEX is defined as the continuous pursuit of holistic operational improvement, in terms of both effectiveness and efficiency, based on balanced performance evaluation and organizational learning.

Operational Excellence Programs: According to (Liker, 2004), an OPEX program is a “sophisticated system of production in which all parts contribute to a whole. The whole at its roots focuses on supporting and encouraging people to continually improve the processes they work on” (p. 34). By drawing on (Bortolotti, Boscari et al., 2015; Friedli et al., 2013; Hadid & Mansouri, 2014; Shah & Ward, 2007), who adopt a social-technical perspective on OPEX programs, this view is specified for this dissertation. OPEX programs are defined as a set of interrelated people-oriented and operations-oriented practices that, when being implemented effectively, can facilitate increased operational performance based in the involvement of employees in the continuous improvement of the processes that they work on.

Management Control: The management control (MC) literature conceptualizes MC in different contexts. (Dornbusch et al., 1975; Ouchi, 1977) define MC as an evaluation process for directing organizational behavior. (Langfield-Smith, 1997) focus on the means applied to exert MC and define it as the formal or informal mechanisms that are used to maintain or alter patterns in organizational activity. This dissertation builds upon both perspectives and define MC as a process of utilizing formal and informal structures for directing human behavior in organizations.

Practices: Practices play a central role in OPEX literature. However, it does not provide a common definition of what OPEX practices constitute. This research builds upon (Schatzki, 2012) and defines practices as organized constellations of activities.

1.3 Scientific Setting

This research addresses a practical problem in the social context, which is derived from both practice and existing literature. To generate new knowledge of scientific nature that can provide practitioners with practical and theoretical guidance, we follow (Ulrich, 1982, 1984) understanding of business studies as applied social science. In contrast to theoretical research, it considers the practical application of theoretical concepts as an integral component of the research.

To address a practical problem, we follow the iterative learning process in accordance with (Baumbach, 1998; Gassmann, 1999; Kubicek, 1977; Tomczak, 1992) (cf. *Figure*

1). According to the authors, it allows to continuously enrich preliminary theoretical understanding based on practical insights. It further helps incorporate the social context for the study of the research problem.

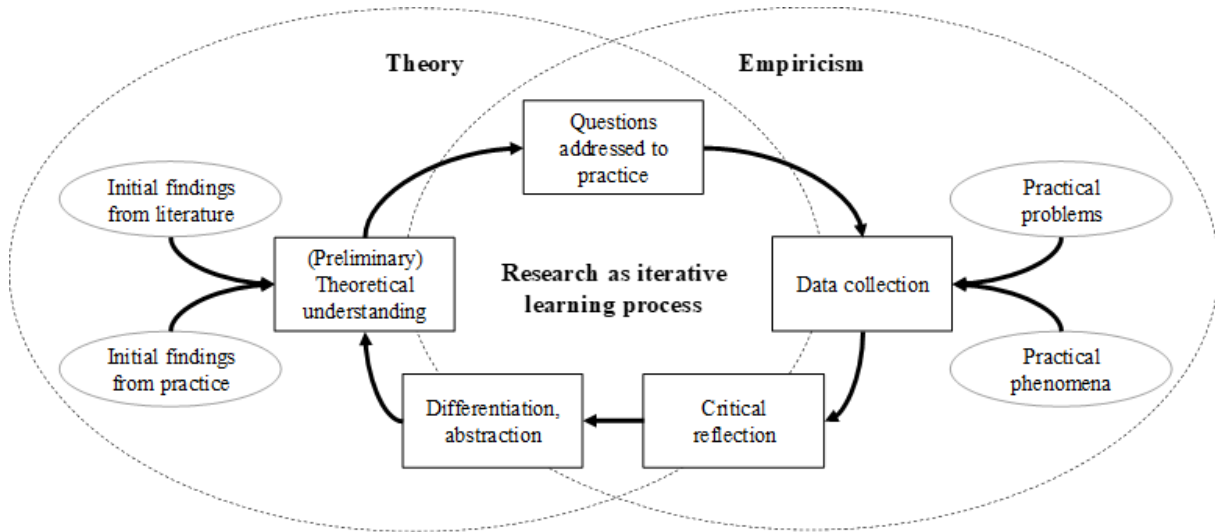


Figure 1: Iterative learning process (Kubicek, 1977), adapted from (Gassmann, 1999)

Following the iterative learning process, first, a practical problem that should be addressed is identified (cf. chapter 1.1). An initial theoretical understanding of the research problem is developed from a review of existing literature as well as from practical observations. This initial theoretical understanding provides the basis for defining research questions that seek to address the identified practical problem. It further forms the basis for developing a theoretical model that can be empirically studied.

The empirical research as part of this dissertation follows a mixed-methods approach. According to (Creswell, 2014), this approach is well suited to get a comprehensive understanding of multifaceted and complex phenomena. The socio-technical interplay between the interrelated people-oriented and operations-oriented OPEX practices that will be studied in this research can be characterized as such practical phenomena. The mixed-method approach uses qualitative and quantitative methods in an exploratory sequential process, which means that it uses the results of one method to better understand or expand the findings of the other (Creswell, 2014). The method triangulation therefore integrates different perspectives on the studied phenomenon and acknowledges the limitations of a singular method approach for the respective phenomenon (Bryman & Bell, 2011). Presenting results from different perspectives, even potentially discrepant ones, contributes to greater credibility and validity of the research, since reality is also composed of different perspectives (Creswell, 2014).

Finally, from studying the theoretical model empirically based on a mixed-method approach, a theoretical framework for impacting SFB is constructed from both theoretical abstraction and reflection of the research findings.

1.4 Research Questions

To address the identified research problem, this dissertation focuses on the role of management for impacting SFB in the context of pharmaceutical OPEX programs.

On the one hand, the shop floor is the primary place of value creation, as (Liker, 2004) points out. (Fullerton et al., 2013) further suggest that the achievement of OPEX goals relies on the shop floor worker's participation in timely and effective decision-making. The behavior of the workers on the shop floor therefore influences the effectiveness and efficiency of the operations.

On the other hand, the management plays a crucial role for overall OPEX program success, based on its ability to influence organizational behavior. According to (Crossman, 2010), failure to truly engage the workforce and non-supportive leadership are the key reasons why change initiatives, such as OPEX programs, fail. The author therefore emphasizes both the importance of workforce behavior and the critical role of management in influencing it. The main research question to be answered is, therefore, as follows:

How can managers impact shop floor behavior in the context of pharmaceutical Operational Excellence programs?

To answer the main research question, four sub research questions (SRQ) are defined. The first sub research question seeks to identify relevant means for impacting SFB in the context of pharmaceutical OPEX programs based on MC literature. SRQ 2 aims at identifying pharma-specific barriers for impacting SFB for OPEX. The subsequent SRQ 3 is directed at understanding the role that MB plays for supplementing MC in pharmaceutical OPEX programs. Finally, SRQ 4 aims at understanding performance effects of the MC applied in pharmaceutical manufacturing firms.

SRQ 1: What are relevant dimensions of Management Control?

To address our research problem, the first sub research question seeks to identify dimensions of people-oriented OPEX practices that managers can utilize to direct SFB

in the context of pharmaceutical OPEX programs. As OPEX literature lacks a uniform conceptualization of these people-oriented practices, we draw on the related stream of MC literature and conceptualize respective dimensions.

The MC dimensions that will be identified in the first step, form the basis for addressing subsequent research questions. On the one hand, they can guide the identification of supportive MBs that supplement the identified MC dimensions (SRQ 3). On the other hand, they provide the basis for investigating the performance effects of exerting MC in the context of pharmaceutical OPEX programs (SRQ 4).

SRQ 2: What are barriers for Operational Excellence behavior on the shop floor in pharmaceutical manufacturing?

The second sub research question acknowledges the recognized importance of contextual factors in the existing OPEX literature. By identifying contextual barriers for impacting SFB in the context of pharmaceutical OPEX programs, we seek to develop an in-depth understanding of the peculiarities of the pharmaceutical manufacturing environment for directing SFB in the context of pharmaceutical OPEX programs. Identifying a set of contextual barriers that are pharma-specific is further intended to provide a basis for evaluating the feasibility of distinct MBs for directing SFB for OPEX (SRQ 3). The barriers that will be identified also provide a basis for studying behavioral implications of the identified MC dimensions in our research context.

SRQ 3: How can managers support Management Control with management behaviors in the context of pharmaceutical OPEX programs?

The third sub research question aims at identifying MBs that can supplement the application of MC in terms of adequately impacting SFB. To identify such MBs, we plan to identify, in a first step, MBs that are applied in pharmaceutical OPEX programs for directing SFB. In a subsequent step, we seek to critically reflect the empirically derived MBs in terms of their potential for supplementing MC, based on prior identification of potential unintended consequences of MC.

SRQ 4: What are performance effects of relevant Management Control dimensions in the context of pharmaceutical OPEX programs?

The last sub research question seeks to evaluate the relation between MC, operations-oriented OPEX practices and operational performance in the context of pharmaceutical OPEX programs. From reviewing existing OPEX literature, we find that only few studies empirically investigate the effects of individual people-oriented practices, including MC. In addition, to the best of our knowledge no existing research investigates

potential moderation effects of MC on the implementation of other OPEX practices. Existing OPEX research, therefore, provides limited empirical insights into the role that MC plays for OPEX programs that practitioners can build upon to tailor the MC system to facilitate operational improvements. By studying the performance effects of MC in the context of pharmaceutical OPEX programs, we set out to contribute to closing these gaps. Specifically, we seek to derive both theoretical and practical guidance for impacting SFB with pharmaceutical OPEX programs in a way that facilitates high levels of operational performance.

1.5 Thesis Structure

This thesis is structured along eight research activities that address the identified research problem in accordance with the outlined iterative learning process. The research activities are depicted in *Table 1* together with both the respective data source and the intended result.

Table 1: Overview of Research Activities

Research Activities	Data Source	Intended Result
Activity 1: Review of literature	Literature	Theoretical foundation
Activity 2: Research Model Development	Literature, research group work	Theoretical research model & list of relevant MC dimensions
Activity 3: Data collection	Research group work, expert interviews, St.Gallen OPEX Benchmarking	Adequate empirics for research project
Activity 4: Construct operationalization	Literature, St.Gallen OPEX Benchmarking	Measurement instruments for quantitative analysis
Activity 5: Identification of barriers	Literature, research group work, expert interviews	List of barriers in pharmaceutical manufacturing
Activity 6: Identification of supportive Management Behavior (MB)	Literature, research group work, expert interviews	Understanding of role of MB and MC in pharmaceutical OPEX programs & list of supportive MB
Activity 7: Analysis of performance effects of Management Control (MC)	St.Gallen OPEX Benchmarking	Actual performance effects of MC for pharmaceutical OPEX programs (direct & indirect effects)
Activity 8: Critical reflection and abstraction	Literature, research group work, expert interviews, St.Gallen OPEX Benchmarking	Framework for impacting shop floor behavior with pharmaceutical OPEX programs

The theoretical foundations are presented in chapter 2. Chapter 2.1 outlines the foundations of OPEX literature, covering the historic development as well as relevant OPEX success factors. Chapter 2.2 presents MC constructs in the existing literature as well as relevant MC frameworks.

Next, chapter 3 synthesizes existing knowledge from OPEX, MC and structuration research. First, the structuration theory is introduced in chapter 3.1 as the theoretical grounding for this research, based on an identified lack of adequate theoretical foundation in OPEX and MC literature for addressing the research problem. In a second

step, the theoretical implications are translated in chapter 3.2 into a generic research framework. Finally, the research framework is developed into a detailed research model in chapter 3.3.

Chapter 4 outlines the set-up of the mixed-method approach for studying the research problem empirically. First, overview of the research setting is provided in chapter 4.1. Subsequently, the approach to both data collection and construct operationalization is outlined in chapter 4.2 and chapter 4.3 as a basis for the quantitative analyses as part of this dissertation.

Next, chapter 5 presents the findings of the empirical research activities. The findings of the qualitative analyses concerning contextual barriers respectively supportive management behaviors, are presented in chapter 5.1 and 5.2. Chapter 5.3 presents the findings from quantitative analysis in terms of performance effects of MC. The chapter closes with the development of the framework for impacting SFB and a validation of the empirical findings (chapter 5.4 and 5.5).

Finally, chapter 6 elaborates on the managerial implications, theory and practice contribution as well as limitations and outlook of the research.

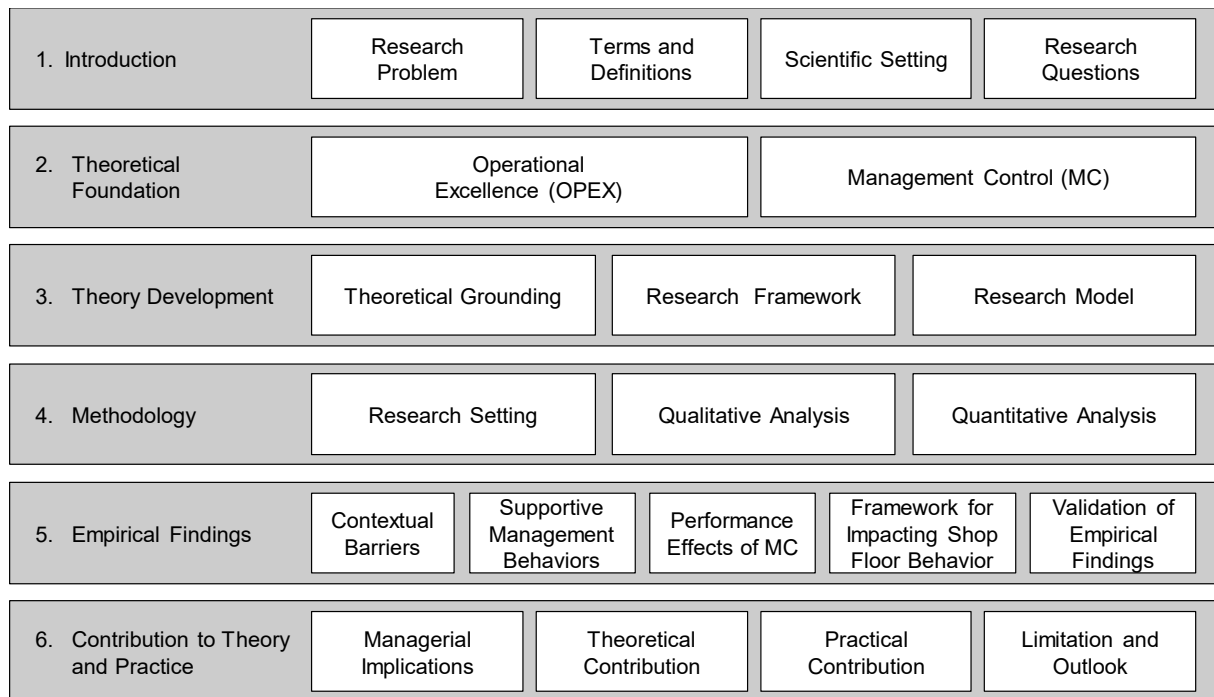


Figure 2: Thesis Structure

2 Theoretical Foundations

This chapter outlines the state of research that this dissertation seeks to extend. It builds upon the existing body of knowledge contained in both the OPEX literature as well as the MC literature. Dealing with two mature research fields, the primary purpose of this chapter is to provide a basis for synthesizing the two existing bodies of knowledge in order to build a solid foundation for addressing the identified research problem. This includes uncovering both the existing state of research as well as potential research gaps. As recommended by (Webster & Watson, 2002) for well-established research fields, our literature review is informed by existing meta-analysis and literature reviews. The results from the literature review compile a thorough knowledge base, which will be further expanded as this research progresses along the previously outlined iterative learning process.

2.1 Operational Excellence

“It takes years to arrive at an elevated ‘new normal’. And it will begin to come apart the very next time leadership and the team takes a day off from this relentless quest for excellence.”

Larry Fast²

OPEX builds upon the body of knowledge on both Quality Management (QM) and Lean Production (LP) (Seghezzi et al., 2013). It relies on the continuous pursuit of balanced operational improvement in terms of effectiveness and efficiency that is based on organizational learning (Friedli et al., 2013). Involving every organizational member in timely and effective decision-making for continuous improvement of organizational processes, therefore, represents an important feature for OPEX. In the following, we therefore outline the underlying concepts and practices of OPEX based on the historic development of OPEX.

2.1.1 World Class Manufacturing

(Wheelwright & Hayes, 1985) introduce the concept of world class manufacturing (WCM) as a descriptive framework for understanding how superior manufacturing capabilities can act as a source of competitive advantage. The authors observe that the production systems of Japanese manufacturers resemble a key success factor. Based on

² Fast (2015)

this observation the authors suggest that the path towards manufacturing excellence involves four distinct stages of effectiveness. According to the authors, the stage of a manufacturer can further be determined based on its view on workforce management regarding five criteria, including command and control.

Table 2 depicts the proposed alternative views on workforce management along the four suggested stages of manufacturing effectiveness. It shows that stage four, which depicts the most effective stage, is distinct from the preceding stages in several regards. According to the authors, workforce management of stage four companies is, overall, directed more towards enabling problem solving and organizational improvement, instead of focusing solely on process stability. As a result, they focus more on organizational learning and less on command and control. The operations of these companies are furthermore worker dependent, which reflects the critical role that workers play for facilitating a learning organization. In a similar vein, they also put a stronger emphasis on systems and values, to the neglect of direct control in terms of supervision. Finally, management of attention is identified as more appropriate compared to management of effort, which can be viewed as a shift in operational constraints along the transition towards manufacturing excellence, from worker availability initially to worker contribution to CI.

Table 2: Perspectives on workforce management, adapted from (Wheelwright & Hayes, 1985)

Stage (1), (2) and (3)	Stage (4)
Command and control	Learning
Management of effort	Management of attention
Coordinating information	Problem-solving information
Direct (supervisory) control	Indirect (systems and values) control
Process stability/worker independence	Process evolution/worker dependence

(1) Minimize manufacturing's negative potential, (2) Achieve parity with competitors

(3) Provide credible support for business strategy, (4) Pursue a manufacturing base competitive advantage

To reach the fourth stage, the authors identify a set of critical practices, which include competing through quality, workforce participation or incremental improvement approaches. At the same time, the authors observe that backsliding from higher to lower stages, for instance due to a lack of engagement and management commitment, represents a reason why only few companies achieve manufacturing excellence. (Wheelwright & Hayes, 1985) therefore conclude that a key challenge for reaching the last stage depicts sustaining a focused effort for excellence over a long period of time.

2.1.2 Quality Management

“If you have a stable system, then there is no use to specify a goal. You will get whatever the system will deliver. A goal beyond the capability of the system will not be reached.”³

William E. Deming

The body of knowledge on QM builds the foundation for OPEX (Seghezzi et al., 2013). QM has been a key source of superior manufacturing performance in the past decades (P. Kumar et al., 2018). It embeds modern quality improvement practices within a managerial framework, such as statistical control, thus making quality techniques and practices operational for OPEX improvements (Bisgaard, 2008). In the past decades, several predominantly American and Japanese authors prepared the ground for the evolution of today’s QM systems.

(Feigenbaum, 1956) introduced the concept of Total Quality Control (TQC), which views quality as the customer’s perception of product and service characteristics, as opposed to an engineering or manufacturing determination. The author further recognizes quality performance as a matter of attitude in organizations and emphasizes that quality is everybody’s job. By emphasizing the crucial role of all organizational members for quality improvements and the need for CI, (Feigenbaum, 1956) contributed significantly to the subsequent evolution of TQC into TQM (Total Quality Management) (Fields et al., 2014).

(Ishikawa, 1985, 1994) contributed significantly to the development of quality tools. Among others, the author introduces a renowned cause-and-effect diagram, which is used for process analysis⁴. The author believed that standards are not enough to ensure quality but are rather an interim stop between individual improvements on the journey towards excellence. Drawing on (Feigenbaum, 1956), the author further developed the concept of companywide quality control, which places the human factor at the heart of QM. Further contributions include the introduction of quality circles as a problem-solving approach.

Next, (Crosby, 1979) defines quality as conforming to requirements. The author suggests that quality has a performance standard of zero defects, thereby rejecting the concept of acceptable levels of quality. In addition, the author further identifies fourteen steps to create quality, which highlight the importance of goal setting, communications, rewards, and systems to measure quality throughout the organization.

³ Deming (1986)

⁴ The cause-and-effect diagram is also known as Ishikawa diagram

(Juran, 1988) views quality as fitness for use and highlights the importance of determining customer needs accurately to prevent over or under specification. The author puts control and improvement into perspective by identifying control as the basis of improvement. Even though the author recommends the use of statistical control, he also warns against a tool-driven approach. As a suitable alternative, the author suggests a human centric approach to managing quality (Oakland, 1995).

(Deming, 1982) provides the basis for linking quality and OPEX. Quality is defined as a “predictable degree of uniformity and dependability, at low cost, suited to the market” (Deming, 1982, p. 229). The author turned against many of the contemporary management views (Seghezzi et al., 2013), which assumed an economic trade-off between productivity and quality. The author concludes that by reducing undesirable variation, quality improvements will inevitably lead to lower cost and higher productivity, which he exemplified by a chain reaction (Deming, 1986). This is in line with (Ferdows & Meyer, 1990), who suggest that quality improvements will ultimately lead to increased cost efficiency by improving reliability and speed. However, there is no scientific consensus regarding the relation between quality and other performance dimensions. In fact, contrasting empirical research focusing on the relation between QM, cost performance and productivity in manufacturing companies exist (Grössler & Grübner, 2006). A major contribution of (Deming, 1986) lies in linking of quality control practices with the wider management system. In his seminal work, the author suggests that there is “a stable system of trouble in a manufacturing plant” and that “because the system is stable, improvement of quality is the responsibility of the management” (Deming, 1986) (p. 1). To transform the American industry towards enhanced quality and productivity, the author condensed his teachings into a total of fourteen lessons management. One of the concepts, which gained a strong foothold across industries for decision making and management of improvement is Deming’s conceptualization of the Shewart cycle⁵, which depicts four essential steps of CI, namely plan, do, check, and act (cf. *Figure 3*) (Seghezzi et al., 2013).

⁵ Deming (1986) consistently referred to the cycle as the Shewart cycle with reference to Shewart (1939). As the author points out, “it went into immediate use in Japan under the name of the Deming cycle, and so it has been called there ever since.” (Deming (1986) (p. 74)

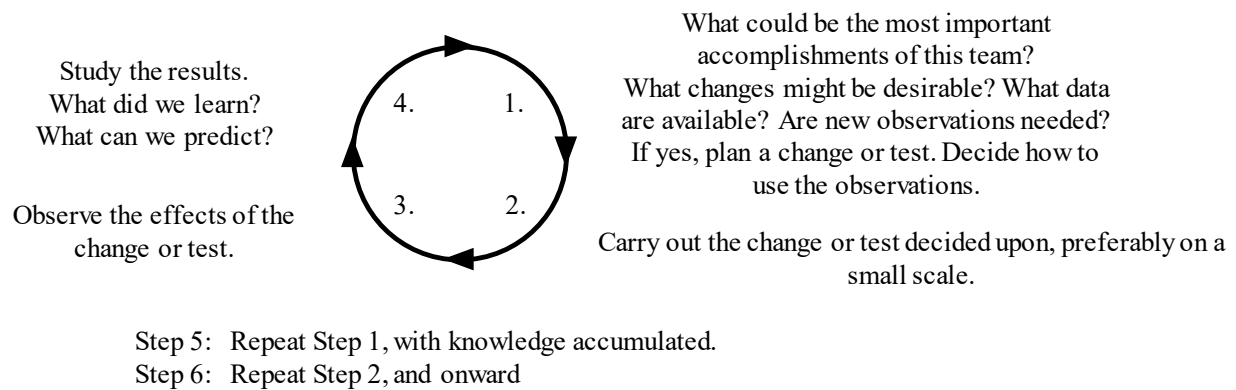


Figure 3: The Shewhart cycle (Deming, 1986)

Based on the outlined work of the aforementioned QM experts, scholars and practitioners have drawn from a number of principles, practices and systems to achieve superior business performance based on quality, with considerable overlap to concepts applied for implementing LP, including CI, Six Sigma⁶, Just-in-time (JIT), Total Productive Maintenance (TPM) and TQM (P. Kumar et al., 2018). Accordingly, QM systems have sometimes also been referred to, more broadly, as frameworks for business excellence assessment (Seghezzi et al., 2013). Thus, there is no clear delineation in literature between principles, practices and systems of QM from those of LP (Carvalho et al., 2017).

2.1.3 Lean Production System

“If you think of ‘standardization’ as the best you know today, but which is to be improved tomorrow – you get somewhere. But if you think of standards as confining, then progress stops.”⁷

Henry Ford, 1926

(Shah & Ward, 2007) view Lean Production Systems (LPS) as integrated socio-technical systems, which aim at eliminating waste by reducing internal or external variability. Similarly, (Liker, 2004) consider supporting and encouraging all employees

⁶ Six Sigma is a quality improvement method for variation reduction, which is based on the so called DMAIC process. It comprises the five steps *Define, Measure, Analyze, Improve* and *Control* (Dahm and Brückner, 2014)

⁷ Ford and Crowther (1988)

to continuously improve the processes they work on the main purpose of LPS. The authors further view LPS as a “sophisticated system of production, in which all of the parts contribute to a whole.” (p 34).

Different approaches to conceptualizing LPS exist in LP literature. Some conceptualize LP from a philosophical viewpoint, in terms of guiding principles or overarching goals (Womack & Jones, 2003). Others conceptualize it in terms of management practices, tools, or techniques (Shah & Ward, 2003). Building upon the latter, LPS can from a socio-technical perspective be viewed as comprised of two mutually dependent components (Sugimori et al., 1977). According to the authors, it includes on the one hand a technical component, which focuses on waste reduction and delivery performance. On the other hand, it comprises a social component, which focuses on engaging the workforce in OPEX. As outlined by (Bortolotti, Boscari et al., 2015), LPS can thus be viewed as being comprised of OPEX practices with both a technical focus and a social focus (cf. *Table 3*).

Table 3: Focus of relevant OPEX practices, adapted from (Bortolotti, Boscari et al., 2015)

OPEX Practices	OPEX Literature
<i>Technical focus</i>	
Setup time reduction	(1), (2), (3), (4), (5), (6)
Just-in-time (JIT) supplier delivery	(1), (3), (4), (6)
Equipment layout for flow	(1), (3), (4), (5), (6)
Pull system	(1), (2), (3), (4), (5), (6)
Statistical process control (SPC)	(1), (2), (4), (5), (6)
Total Productive Maintenance	(1), (3), (4), (5), (6)
<i>Social focus</i>	
Problem solving (small groups)	(2), (4), (6)
Employee training	(1), (2), (4), (5), (6)
Top management leadership	(1), (2), (4)
Employee involvement	(1), (2), (5), (6)
Continuous improvement	(4), (5)
Supplier partnership	(1), (2), (4), (6)
Customer involvement	(1), (2), (4), (6)

(1) (Cua et al., 2001), (2) (Flynn et al., 1995), (3) (Mackelprang & Nair, 2010), (4) (Matsui, 2007), (5) (Shah & Ward, 2003), (6) (Shah & Ward, 2007)

The blueprint for LPS is the Toyota Production System (TPS) (Liker, 2004; Womack et al., 1990). Its origins can be traced back to Japan in the period after the Second World War, when Japanese manufacturers lacked resources to rebuild devastated facilities (Bhamu & Sangwan, 2014). Toyota was the leading company to adopt and further develop modern quality management and productivity improvement concepts taught by American quality experts as well as U.S. forces present in Japan during that time (Liker, 2004; J. Singh & Singh, 2012). By building upon these teachings, Toyota became one of the most effective and efficient manufacturers in the world (Bhamu & Sangwan, 2014).

Some of the TPS practices have already been recognized in traditional manufacturing approaches. While the existing OPEX literature commonly views the TPS as a counter-intuitive alternative to Henry Ford's traditional manufacturing model (Womack et al., 1990), some of its key principles, such as workflow or continuously improving standards, have in principal also been recognized by Henry Ford (Ford & Crowther, 1988). Thus, it is not individual practices that make up the TPS, but their joint composition. Drawing on (Ohno, 1988; Shingo, 1989; Womack et al., 1990), (Liker, 2004) portrays the TPS in a similar vein as a house. At its heart, it focuses on CI based on the foundational elements stable and standardized processes, visual management, a levelled production and lean philosophy (cf. *Figure 4*).

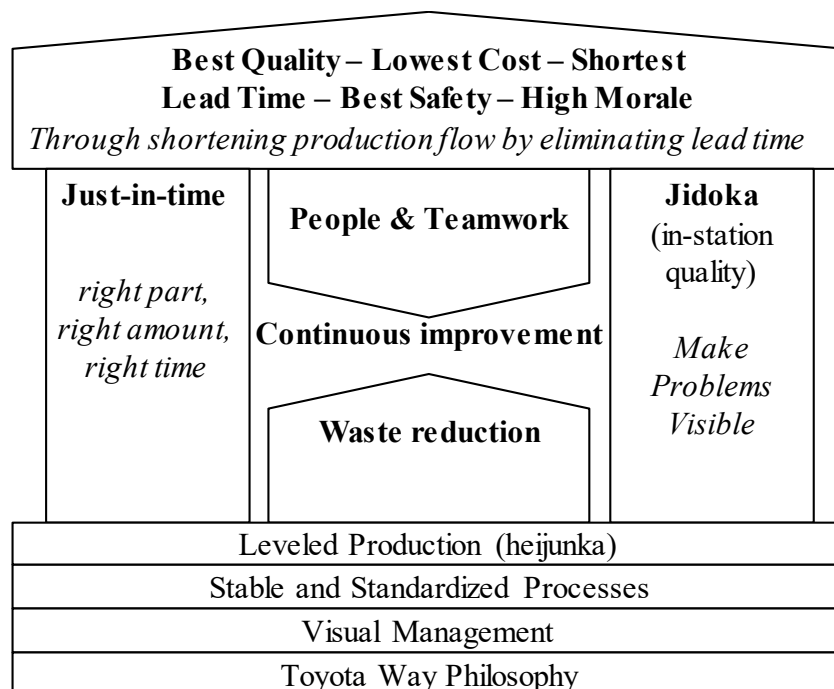


Figure 4: The Toyota Production System (TPS), adapted from (Liker, 2004)

(Liker, 2004) describes the foundations of TPS based on the fourteen principles that are outlined in *Table 4*. They outline the TPS philosophy and its approach to stable and standardized processes, to developing people and partner as well as to problem solving and organizational learning. While many of the fourteen principles appear to focus on the technical component, (Ohno, 1988) suggests that the TPS has been misinterpreted as a workflow system, similarly to the Ford system, which introduced the workflow system and automation. Instead, it should be viewed as an overall management system. The author points out, that while the Ford system in many regards forces the work to flow, the TPS is more reflective of Ford's true intention. According to the author, the TPS is not about forcing the work to flow, but about achieving real workflow by utilizing the technical component (JIT) on the one hand, and the social component (autonomation) on the other hand "as both the means of realizing the system as well as the end" (Ohno, 1988, p. 101).

Table 4: Fourteen principles of the Toyota Way, adapted from (Liker, 2004)

Focus	Principle
Philosophy	1. Base your management decisions on a long-term philosophy, even at the expense of short-term financial goals.
Process	2. Create continuous process flow to bring problems to the surface. 3. Use "pull" systems to avoid overproduction. 4. Level out the workload. 5. Build a culture of stopping to fix problems, to get quality right the first time. 6. Standardized tasks are the foundation for continuous improvement and employee empowerment. 7. Use visual control so no problems are hidden. 8. Use only reliable, thoroughly tested technology that serves your people and processes.
People and Partners	9. Grow leaders who thoroughly understand the work, live the philosophy, and teach it to others. 10. Develop exceptional people and teams who follow your company's philosophy. 11. Respect your extended network of partners & suppliers by challenging them and helping them improve.
Problem solving and learning	12. Go and see for yourself to thoroughly understand the situation. 13. Make decisions slowly by consensus, thoroughly considering all options and implement decisions rapidly. 14. Become a learning organization through relentless reflection and continuous improvement.

Continuous improvement

Both LP and QM literature emphasize the critical role of CI for superior and sustainable manufacturing performance (Deming, 1986; Juran, 1988; Ohno, 1988; Shingo, 1989). It

comprises both incremental and larger improvements and aims at eliminating all waste along the value chain (Liker, 2004).

CI is considered to be not determined by great investments but by the involvement and commitment of every organizational member (Robinson, 1990; J. Singh & Singh, 2012). To facilitate effective CI, (Ishikawa, 1985) thus emphasizes the critical role of skills and experience over standards and policies, suggesting that “standards and regulations are always inadequate” and “it is experience and skill that make up for inadequacies in standards and regulations” (p. 66). However, the author does not discard standards in general. Instead, he suggests that standards should be followed, until they prove insufficient, which should be the trigger for CI. In a similar vein (Imai, 1997) outlines three phases of improvement, which can be viewed as a roadmap for OPEX, comprising the phases innovation, standardization and improvement (cf. *Figure 5*).

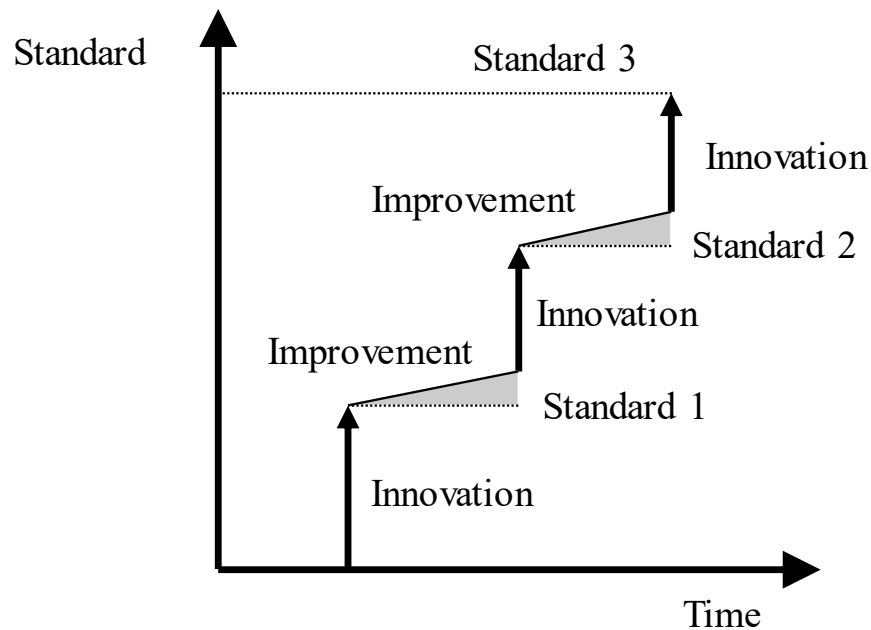


Figure 5: Three phases of improvement, adapted from (Imai, 1997)

Despite its origin in the post Second World War era in Japan, the existing OPEX literature suggests, that CI will also remain crucial to stay competitive in an ever-changing market environment (Schroeder & Robinson, 1991). In addition, with regards to the potential of incremental improvements compared to disruptive innovations, the authors point out CI may not only require less investments than technology breakthrough innovations but may also lead to higher performance gains. To date, CI therefore represents one of the main paradigms in OPEX literature.

2.1.4 OPEX Success Factors

Despite numerous studies examining the effects of OPEX programs on firm performance, still relatively little is known about the factors that influence their successful implementation. Researchers have therefore speculated extensively about what makes OPEX programs succeed or fail.

Existing OPEX research recognizes the potential influence that various factors may have on the effectiveness of OPEX implementation. While the predominate view is that OPEX practices are universally beneficial (Womack et al., 1990), existing OPEX research found mixed performance returns from OPEX programs (Mackelprang & Nair, 2010). Some researchers, therefore, point out that the effectiveness of OPEX programs may be depended on various influencing factors. The universal benefits of OPEX programs are therefore up for debate (Wiengarten et al., 2015).

Previous OPEX research has scrutinized potential reasons why OPEX programs fail. Existing research has studied, among others, the underlying principles of OPEX (Womack et al., 1990), barriers for OPEX (Marodin & Saurin, 2015), or components and practices of OPEX programs, as previously outlined (Shah & Ward, 2003). Some scholars also consider contextual factors as potential determinants of a successful OPEX implementation (Lukman & Salim, 2017; Panwar et al., 2015). Yet, despite the various research on influencing factors for OPEX, empirical research on their effects is still scarce. It is, among others, this remaining lack of knowledge on cause-and-effect relations of relevant OPEX influencing factors that spark an ongoing interest in research on OPEX implementation.

Potential reasons why OPEX programs succeed, or fail are manifold. They include, among others, a lack of focus on managing human resources (Agarwal et al., 2013), high complexity associated with OPEX implementation (Lander & Liker, 2007), or existence of contingency factors limiting its potential (Bortolotti et al., 2013). In terms of the latter, (Shah & Ward, 2003) found that the magnitude of performance gains from OPEX programs vary significantly depending on the organizational context. A comprehensive overview of potential success factors for OPEX implementation is provided by (Netland, 2016), which underline the complexity of implementing OPEX (cf. *Table 5*).

Table 5: Critical OPEX success factors, adapted from (Netland, 2016)

#	Critical Success Factor	Attributes
1	Lead actively	Personal commitment; initiative; passion; role modelling.
2	Participate personally	Visibility; participation in Gemba; demonstration of benefits.
3	Educate employees	Training on tools, methods and principles; formal OPEX training for shop floor personnel.
4	Educate managers	OPEX knowledge as prerequisite for coaching; OPEX philosophy as basis for successful implementation.
5	Communicate, inform and discuss	Regular communication of vision, strategy, targets, performance; permanent dialogue; shop floor communication.
6	Set targets and follow-up	Link between OPEX program, targets and performance; OPEX KPIs for all employees.
7	Involve and support employees	Involvement of every employee in problem solving; support of employees' initiatives for both hard and soft savings; listening.
8	Dedicate human resources	OPEX implementation team; OPEX implementation organization; regular strong OPEX governance (OPEX council).
9	Use OPEX tools and methods	Demonstration of benefits from tools; use of root cause analysis (RCA); visualization of deviations (5S).
10	Integrate OPEX in everyday business	Daily commitment; use of OPEX as a systematic improvement system; use of OPEX as ways of work instead of project.
11	Develop vision and roadmap	Goal and strategy setting; long term policy deployment; transformation road map; strategy/plan for sustainability.
12	Use rewards and recognition	Motivation and reward of operators; incentive program; definition of recognition system for the best performers.
13	Monitor and audit implementation	Regular internal audits; periodic OPEX implementation reviews; frequent follow-ups.
14	Standardize and manage discipline	Definition of OPEX program standards; obligation to execute; disciplinary follow-ups.
15	Find and share best practices	Encouragement of best practices; friendly competition; best practice sharing.
16	Stepwise approach	Step by step enforcement and implementation of improvements; safeguarding of improvements; focus on effort.
17	Focus on areas and prioritize activities	Focus (few priorities or areas); reduction of KPIs; follow-up on the weakest OPEX program modules.
18	Invest time and money	Funding of worker-initiated projects; allocation of time and resources.
19	Benchmark others	Duplication of high performing plants; external factory visits; internal benchmarking.
20	Emphasize team concept	Team concept introduction; goal-oriented teams; teamwork spirit (everything is possible).
21	Use external experts	Long term presence; external and internal consulting support; OPEX experience of external consultants.
22	Hold regular implementation meetings	Regular management meetings; weekly updates (department); Information sharing and action plan review meetings.
23	Emphasize safety and job attractiveness	Changes for greater good (versus financial gains); improvement of working place and environment of operator; communication on targets and results in well-being (e.g. ergonomics, quality).
24	Commit corporate management	Top management push (not local); global necessity and decision to pursue OPEX; commitment and resources from external hierarchy.

2.2 Management Control

“I sometimes hear the argument that the measures and controls used in organizations are insufficiently powerful to produce the hoped-for results. I rarely find this to be the case. By contrast, I would argue that controls and performance measures are, if anything, rather too powerful mechanisms for influencing behavior.”⁸

David Otley

The existing literature highlights the central role of MC within management research. (Braverman, 1974) argue that management rests on “the control over work through the control over the decisions that are made in the course of the work” (p. 107). Yet, literature does not clearly distinguish different types of management control and has been criticized in general for being ill-defined (Ferreira & Otley, 2009; Tessier & Otley, 2012). The following sub chapters provide an overview of relevant control constructs in literature. In a first step, MC is conceptualized. Subsequently, relevant MC constructs as well as MC frameworks are introduced.

2.2.1 Conceptualization of Management Control

The control literature distinguishes organizational control from MC, even though, they are not clearly distinguishable, according to (Ouchi, 1977). As a result, MC research has been criticized for artificially separating MC from strategic and operational control (Langfield-Smith, 1997). The former dates back to (Child, 1973; Cyert & March, 1963), while the latter has emerged from the management accounting literature (Tessier & Otley, 2012). Organizational control has been defined as “any mechanism that managers use to direct attention, motivate, and encourage organizational members to act in desired ways to meet an organization’s objectives” (Long et al., 2002, p. 198). In a similar vein, MC has been described as the process for influencing behavior (Flamholtz et al., 1985), or as the “process of assuring that the organization does what the management wants done” (Anthony, 1956, p. 268).

In this research, MC is viewed as the formal or informal means that are applied to maintain or alter patterns in SFB. This is in line with (Langfield-Smith, 1997), who describe MC as “means for gaining cooperation among collectives of individuals or

⁸ Otley (2003)

organizational units [...] and channeling those efforts toward a specified set of organizational goals” (p. 208). Following (Bititci et al., 2018), who draws on (Child, 1973), MC is further viewed as covering both “rational, planned, bureaucratic and structural elements of the organization” as well as “emergent, cultural and behavioral aspects” that are used in conjunction to direct behavior of shop floor personnel (p. 654).

2.2.2 Management Control Constructs

“Distinguishing between types of controls is a concern that is present in the literature” (Tessier & Otley, 2012, p. 178). MC constructs have been categorized by manifold criteria and at different levels of abstraction. For instance, it has been distinguished by control target, by control mechanism, or by configurations of multiple control mechanisms (Cardinal et al., 2010; Langfield-Smith, 1997; Long et al., 2002; Ouchi, 1979, 1980).

(Child, 1973) proposes two opposing approaches to MC. On the one hand, a rational and bureaucratic approach and, on the other hand, a cultural approach (Bititci et al., 2012). In a similar vein, (Tessier & Otley, 2012) distinguish between social and technical controls and further differentiate controls by objective and managerial intention. In contrast, (Ouchi, 1979) and (Franco-Santos & Otley, 2018) distinguish control by degree of formalization into formal and informal controls. This is in line with (Adler & Borys, 1996), who additionally distinguish controls by type of formalization into enabling and coercive controls, which implicitly assess the quality of controls (Tessier & Otley, 2012). (Simons, 1995) distinguishes positive and negative controls in similar fashion. (Burns & Stalker, 1961) and (Chenhall, 2003) differentiate mechanistic controls from organic controls. The latter are viewed by (Adler & Borys, 1996) as specific configurations in term of the control dimensions degree and type of formalization. *Table 6* builds upon research by (Bedford & Malmi, 2015) and provides an overview of relevant MC constructs in MC literature⁹.

⁹ Bedford and Malmi (2015) provide a comprehensive overview of relevant control constructs. They exclude some established constructs for their empirical analysis, based on overlap with other control constructs. For instance, formalization was omitted, because of its close relation to constructs, such as standardization.

Table 6: Overview of management control constructs, adapted from (Bedford & Malmi, 2015)

Author	Context	Control Constructs	Control Mechanisms
(Simons, 1995)	Positive and negative control systems manage tensions between opposing forces, “between freedom and constraint, between empowerment and accountability, between top-down direction and bottom-up creativity, between experimentation and efficiency” (p. 4)	• Diagnostic control system • Interactive control system • Boundary system • Beliefs system	- Monitoring - Norms - Policies and procedures - Values, beliefs and social norms
(Simons, 1987)	Financial performance measures of cost efficiency and effectiveness	• Cost control	- Planning/Budgeting - Reporting - Monitoring
(Bisbe et al., 2007)	Importance of regular involvement in subordinate activities by management to encourage debate, creative behaviors and address strategic uncertainties	• Interactive control system	- Involvement of management in subordinate activities
(Schein, 2004)	Reliance on shared values, norms and beliefs to direct work activities	• Social control • Beliefs system	- Shared values, norms and beliefs
(Ouchi, 1979)	see (Schein, 2004) above	• Social control	- Norms - Authority - Shared values - Beliefs
(Ouchi, 1977)	“Control can be conceptualized as an evaluation process which is based on the monitoring and evaluation of behavior or of outputs” (p. 95)	• Behavior control • Output control	- Policies and procedures - Monitoring and evaluation of process of performance
(Rockness & Shields, 1984)	Impact of controls is dependent on knowledge of the task transformation process (technological uncertainty)	• Input control • Behavior control • Output control	- Social, expenditure budget - Formal rules and operating procedures, scheduling - Market
(Merchant & van der Stede, 2007)	“Taking steps to ensure that employees act in the organization’s best interest by making their actions themselves the focus of control” (p. 76)	• Action controls	- Behavioral constraints - Pre-action reviews - Accountability - Redundancy

2 THEORETICAL FOUNDATIONS

(Merchant, 1985)	Importance of individual accountability for meeting pre-established performance targets	• Tightness	- Targets - Communication of targets - Monitoring - Reward
(Burns & Stalker, 1961)	Different approaches to MC as organizational responses to distinct conditions of stability and change	• Organic/mechanistic	- Formal rules - Standardized operating procedures - Routines
(Chenhall, 2003)	Grouping of MC system elements and control types commonly found in research, in terms of the organic or mechanistic nature of control	• Organic/mechanistic	- See above
(Chenhall & Morris, 1995)	Study of combined effect of organic decision and communication processes as well as formal planning and control systems on performance	• Organic/mechanistic	- Financial reports and review - Information systems
(Adler & Borys, 1996)	Whether employees perceive formalization as positive or negative depends on whether it enables them or coerces their effort and compliance.	• Formal/informal • Enabling/coercive control • Organic/mechanistic	- Written rules and procedures - Documented best practices - Planning, measurement, review
(Broadbent & Laughlin, 2009)	A set of MC mechanisms that facilitate the delivery of organizational goals by influencing people's behavior and performance	• Transactional/relational control	- Planning - Measurement - Review - Reward
(Tessier & Otley, 2012)	Development of Simons' Levers of Control into a revised framework, which organizes social and technical controls into four control systems	• Social/technical control	- Core values, beliefs, norms - Rules, procedures and standards - Goal setting, output controls and cybernetic controls
(Smith & Bititci, 2017)	Emphasis of importance of considering both technical and social perspective on design and use of MC	• Social/technical control	- See above

(Child, 1972)	Structuring of activities, concentration of authority, line control of workflow and relative size of support component as distinctive dimensions of structure in organizations	• Structural control	- Specialization - Standardization - Formalization - Centralization - Span of control
(Ocasio & Wohlgezogen, 2010)	Central role of communication and decision-making channels for distribution of attention and directing organizational behavior	• Structural/ situational control (cultural, outcome, hierarchical, behavior, channel)	- Rules - Resources - Social relationships
(Bruns & Waterhouse, 1975)	Exploration of interaction and relationships of structuring, with budgets	• Autonomy • Centralization/ structuring	- Work roles/specialization - Authority - Budgets - Policies and procedures
(Malmi & Brown, 2008)	Typology of management control systems used to direct employee behavior, distinguishing decision-making and control	• Cultural controls • Cybernetic controls • Administrative controls • Planning • Reward & compensation	- Core values - Beliefs - Norms
(Kober et al., 2007)	See (Simons, 1987) above	• Cost Control	- Variance analysis, cost center
(Ittner et al., 2003)	Broad scope and non-financial performance measures	• Measure Diversity	- Non-financial measures - Balanced scorecard
(Henri, 2006)	See above	• Measure Diversity	- See above
(Macintosh, N. B., Daft, R. I., 1987)	Rules and procedures specifying the means of conducting work activities	• Standardization	- Standard operation procedures

Many of the presented MC constructs share some MC mechanism for directing organizational behavior that underly the MC constructs. Yet, their conceptualization, the assumed relations between MC constructs and their assumed behavioral implications vary widely.

Possible reasons for the lack of consensus regarding the conceptualization of MC constructs include lack of clear differentiation between constructs or inconsistent levels of analysis (Cardinal et al., 2010). Regarding the former, the authors point out that, for example, the concept of the clan is sometimes used synonymously with constructs, such as cultural controls (Merchant, 1985) or social control (Eisenhardt, 1985), whereas other times it is used to describe specific configurations of informal controls (Ouchi, 1979, 1980). On the other hand, in terms of levels of analysis, (Simons, 1995) conceptualization of interactive and diagnostic MC has been criticized for resembling two types of managerial intentions of MC, rather than MC constructs (Tessier & Otley, 2012). Overall, (Cardinal et al., 2010) therefore attributes the lack of empirical MC research in parts to the inconsistent labelling of MC constructs.

2.2.3 Management Control Frameworks

Existing MC research suggests that organizations should maintain a balance between different MC constructs, which can be context dependent (Langfield-Smith, 1997). (Franco-Santos & Otley, 2018) describe two types of MC, directive and enabling MC, which are to be balanced. (Tessier & Otley, 2012) distinguishes technical and social controls as integral elements of MC in organizations that need to be integrated in an adequate manner. (Burns & Stalker, 1961, 1994) suggest, that mechanistic forms of MC are more appropriate in a stable environment, whereas organic forms excel in a dynamic environment. Based on the proposed multiple roles of MC in organizations, different scholars set out to integrate relevant MC constructs into comprehensive MC frameworks, which will be outlined in the following.

(Rotch, 1993) provides an overview of relevant components of MC systems, which are clustered into three groups. The author views MC as “means of gathering data to aid and co-ordinate the process of making planning and control decisions throughout the organization” (p. 192). The author further considers providing decision-support to the entire organization and not only to managers, as a key role of management for influencing organizational behavior. For fulfilling this role, the author identifies twelve components that are viewed as the basis for an effective application of MC. These include the components strategy, structure, performance measurement, direction setting, leadership style or rewards and incentives, as depicted in *Figure 6*.

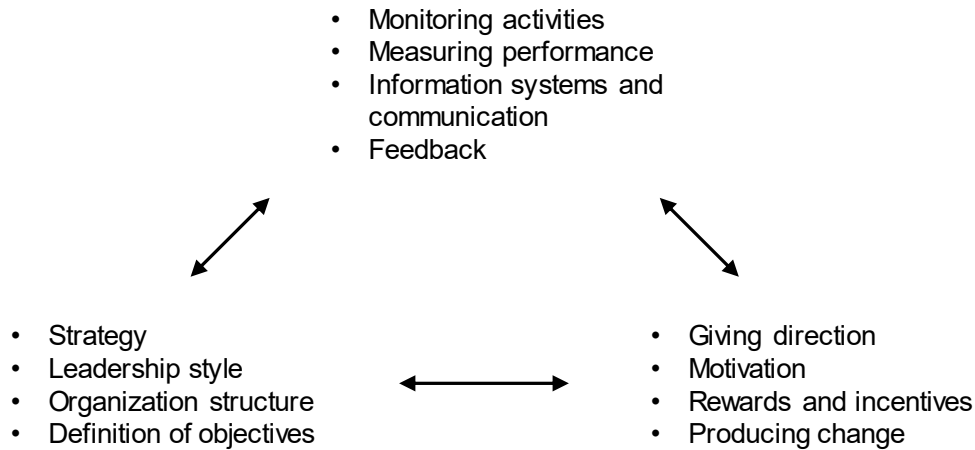


Figure 6: Management control system (Rotch, 1993)

(Malmi & Brown, 2008) view MC as all systems that managers use to direct organizational behavior towards organizational goals. According to the authors, several MC systems are typically in use in organizations, which are not designed and coordinated intentionally and therefore do not resemble a single system. The authors therefore circumvent the use of the term ‘MC systems’ and instead suggest ‘MC system package’ as a more practical term. Based on this view, the authors propose the typology of MC comprising thirteen types of MC. These are further categorized into the five categories cultural controls, planning, cybernetic controls, reward and compensation, and administrative controls, as depicted in *Figure 7*.

According to the authors, cultural controls are described as “values, beliefs and social norms which are established to influence employee behaviour” (p.292). Planning is distinguished into long range planning and action planning, which include defining goals and aligning them across the organization. Next, cybernetic controls are distinguished into the four subcategories budgets, financial and non-financial measurement systems and hybrid systems. Relevant means of control include performance indicators, performance standards to be met, feedback processes and other means that can modify organizational behavior based on quantification of system activities. According to the authors, the primary purpose of rewards and compensation is to motivate organizational members to increasing their performance by influencing direction, duration, and intensity of their efforts. Finally, that authors draw on (Simons, 1987), and view administrative controls as those “that direct employee behavior through the organizing of individuals (organization design and structure), the monitoring of

behavior and who employees are made accountable to for their behavior (governance); and through the process of specifying how tasks or behaviors are to be performed or not performed (policies and procedures)” (p. 292).

Cultural Controls						
Cultural Controls		Values			Symbols	
Planning		Cybernetic Controls				Reward and Compensation
Long range Planning	Action Planning	Budgets	Financial Measurement Systems	Non-Financial Measurement Systems	Hybrid Systems	
Administrative Controls						
Governance Structure		Organization Structure			Policies and procedures	

Figure 7: Typology of Management Control (Malmi & Brown, 2008)

Next, the framework of (Simons, 1995) addresses a recognized overemphasis in control literature on strategy formulation, to the relative neglect of controlling strategy implementation. The framework builds upon the idea of opposing MC systems for managing dichotomies in organizations, such as between empowerment and accountability, or between experimentation and efficiency. Overall, the framework comprises four MC systems (cf. *Figure 8*), two of which are defined as positive levers (interactive control system and beliefs system) and two are defined as negative levers (boundary system and diagnostic control system). First, interactive control can facilitate organizational learning by focusing attention on critical areas, based on the involvement of managers in the decision-making of their subordinates. The belief system aims at providing employees with guidance how to behave and further acts as a source of motivation. Next, the boundary system establishes negative boundaries, which can “enable subordinates to respond to local contingencies autonomously, but within predefined limits” (Bedford & Malmi, 2015) (p. 8). Finally, the diagnostic control system can allow organizations to achieve its goals without constant management oversight, due to the attention that organizational members pay to them (Simons, 1995).

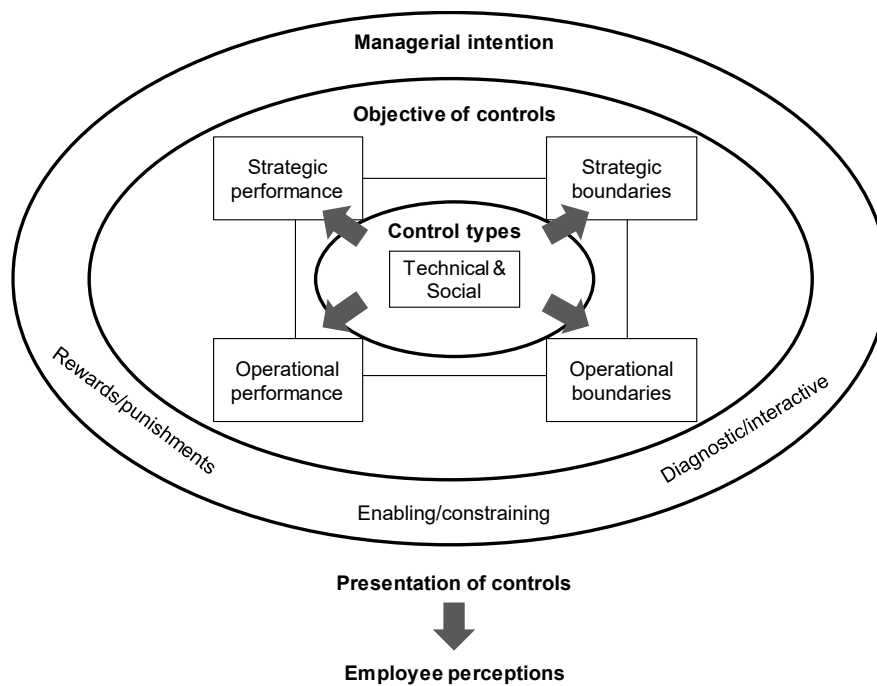


Figure 9: Revised framework of levers of control (Tessier & Otley, 2012)

In the following, the categorization of (Malmi & Brown, 2008) is utilized to structure relevant dimensions of MC in OPEX programs. As outlined in this chapter, MC constructs are categorized in the existing MC frameworks by different criteria and on different levels of analysis. Main criteria include managerial intention or objective (Simons, 1995), effect of controls (Adler & Borys, 1996; Simons, 1995), degree or type of formalization (Adler & Borys, 1996; Langfield-Smith, 1997) or more broadly technical or social nature of controls (Child, 1972, 1973; Malmi & Brown, 2008; Ouchi, 1979; Tessier & Otley, 2012). Against this backdrop, and drawing on (Bedford & Malmi, 2015), the framework of (Malmi & Brown, 2008) is considered an adequate and comprehensive MC typology for this research, since the established MC constructs can be assigned to one of the framework categories. The categorization of MC along the typology of (Malmi & Brown, 2008), as performed by (Bedford & Malmi, 2015), is depicted in Table 7.

Table 7: Categorization of relevant control constructs, adapted from (Bedford & Malmi, 2015)

Construct	Definition
<i>Strategic planning</i>	
Participation	Involvement of subordinates in strategic planning processes.
Mode of planning	Mode of developing the long-term ends and means: ad-hoc, adaptive and emergent, to formalized, deterministic and deliberate.
<i>Cybernetic</i>	
Diagnostic control	Monitoring activity through deviations from pre-set standards of performance.
Interactive control	Regular involvement in subordinate activities by management to encourage debate, creative behaviors and address strategic uncertainties.
Cost control	Financial performance measures of cost efficiency & effectiveness.
Measure diversity	Broad scope and non-financial performance measures.
Tightness	Individual accountability for meeting pre-established performance targets.
<i>Structure</i>	
Integrative liaison devices	Horizontal structural arrangements overlaying traditional functional structures.
Communication	Nature, direction and content of communication patterns: mechanistic to organic.
Decentralization	Locus of authority: centralized to decentralized.
Hierarchy	Vertical differentiation of firm structure: flat to tall.
<i>Policies & procedures</i>	
Boundary system	Statements defining acceptable or unacceptable domains of activity.
Standardization	Rules and procedures specifying the means of conducting work activities.
Autonomy	Work activities conducted in the absence of direct observation or involvement by management.
Pre-action reviews	Processes of scrutinization and authorization prior to activity.
<i>Compensation & Reward</i>	
Performance recognition	Performance-contingent rewards and incentives.
Objective / subjective	Method of determining individual compensation: subjective to objective.
Short-term / long-term	Time horizon used for individual compensation: short to long term.
<i>Cultural</i>	
Belief system	Statements communicating the basic values and premises for action of the firm.
Social control	Reliance on shared values, norms & beliefs to direct work activities.
Socialization	Processes whereby individuals come to appreciate prevailing norms and beliefs.
Selection	Search, evaluation and recruitment of employees according to a set of criteria, such as value alignment.

3 Theory Development

In this chapter, the theoretical model that guides our research is laid out. The previous chapters outlined that existing OPEX literature does not provide adequate theoretical guidance for impacting SFB. To obtain a theoretical model for this dissertation, relevant streams of literatures related to human behavior management are therefore synthesized.

In a first step, the theory of structuration is identified as a suitable theoretical grounding (cf. chapter 3.1). It establishes a link between human behavior and structural aspects of social systems. Said theoretical perspective is the adopted to posit a preliminary research framework for impacting SFB with OPEX programs (cf. chapter 3.2). In a final step, the constituting elements of the derived research framework are specified to obtain a detailed model that guides this dissertation (cf. chapter 3.3). For this purpose, this research draws on both the OPEX and the MC literature.

3.1 Theoretical Grounding

The theory of structuration that is introduced by (Giddens, 1979) provides a unique perspective on human behavior management and builds the theoretical foundation for the research at hand. Among others, it helps put relevant people-oriented OPEX levers in relation with each other. In the following, both the key concepts and the key terms of the theory of structuration are introduced and are further put it in context with corporate OPEX programs.

From Structure and Agency to Structuration

As a starting point for theorizing about structuration, (Giddens, 1979) states that no coherent account exists in literature of the relationship between what are referred to as *structure* and *agency*. Prior attempts to explain human behavior in social systems are therefore viewed as lacking holistic considerations of the interplay between relevant determinants of human behavior in social systems, in terms of adopting either agentic or structuralists perspectives.

To overcome a series of issues in sociological literates related to this proposed dichotomy between agentic or structuralists perspectives, the author reconceptualizes several terms and concepts related to the notions of *agency* and *structure*. As part of this effort, (Giddens, 1979) introduces the *duality of structure* to conceptualize human

interaction in social systems. In the following, the concepts *agency*, *structure* and *duality of structure* are introduced.

According to the author, *agency* refers to social ‘action’ or ‘doing’. Yet, *agency* is not viewed as resembling single activities or discrete acts. Instead, it is viewed as a continuous flow of conduct, which incorporates temporality into the understanding of human action. A critical precondition is thereby that the agent could have acted otherwise at any point in time to (Giddens, 1979).

Structure, in contrast, is viewed as “rules and resources recursively implicated in social reproduction” (Giddens, 1984, xxxi). This view differs from prior conceptualizations in sociological literature in the way the term is understood. It is conceptualized as being “constantly recreated out of the very resources which constitute them” (p. xxiii). *Structure* is considered to further exist as properties of social systems and is therefore also referred to as structural property. It is therefore clearly separated from the concept of *system*, which refers to relations between actors or collectives (cf. Table 8).

Table 8: *Structure, system and structuration in the theory of structuration (Giddens, 1979)*

Structure	Rules and resources, organized as properties of social systems. Structure only exists as ‘structural properties’.
System	Reproduced relations between actors or collectives, organized as regular social practices.
Structuration	Conditions governing the continuity or transformation of structures, and therefore the reproduction of systems.

Finally, *agency* and *structure* are put in relation to each other through the concept *duality of structure*. It proposes that “the rules and resources drawn upon in the production and reproduction of social action are at the same time the means of system reproduction” (Giddens, 1984, p. 19). *Structure* can therefore be viewed as both the medium and the outcome in the production and reproduction of interaction in social systems. The central dimension of this concept is represented by what is called *modality*. *Modality* refers to the “knowledgeable capacities of agents to structural features” (Giddens, 1984, p. 28), which are drawn upon by agents in the production of *interaction*. As suggested by the *duality of structure* concept, *modality* is further viewed as the central dimension for reproducing the structural properties of social systems.

Figure 10 shows the interrelation between the dimensions of *structure*, *interaction* and *modality* that make up social systems, according to (Giddens, 1984). Each of the

three dimensions is further distinguished into three subdimensions. First, *structure* is distinguished into *signification*, *domination*, and *legitimation*. Similarly, the author distinguishes *interaction* into the subdimensions *communication*, *power*, and *sanction*. Finally, *modality* is distinguished into the subdimensions *interpretative schemes*, *facility*, and *norms*.

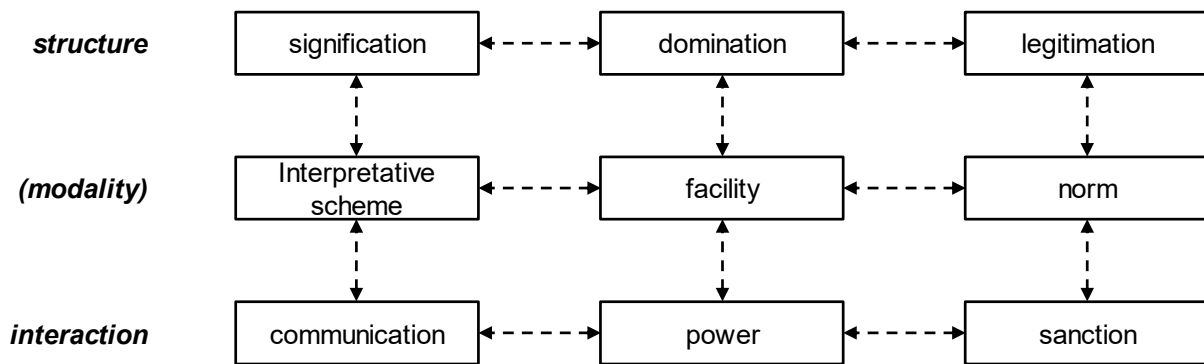


Figure 10: Conceptualization of duality of structure (Giddens, 1984, p. 29)

According to the *duality of structure*, each subdimension of *modality* plays a dual role in the production and reproduction of the three types of *interaction*. *Interpretative schemes*, on the one hand, are drawn upon by organizational members for *communication* and further help provide reasons for activities in terms of *signification* (Giddens, 1984). They are considered incorporated in the stocks of knowledge that actors apply in sustaining *communication*. *Norms*, on the other hand, are applied to *sanction* conduct and further provide the means for *legitimation*. According to (Giddens, 1984), they intersect with *interpretative schemes* in that the stock of knowledge that is drawn upon by organizational members in the production and reproduction of *interaction* are the same that provide *legitimation* or *signification*. Finally, *facility* can be understood in terms of the means which influence autonomy and dependence by shaping *power* relations in social systems.

As emphasized by the author the dimensions depicted in *Figure 10* do not represent a taxonomy of social practices. They are, therefore, not exclusive to specific these practices, but can instead be combined in social practices in differing ways. To illustrate on the example of *structure*, (Giddens, 1979) suggests that *signification* can only be understood in conjunction with *legitimation* and *domination*, and vice versa. Conversely, the author concludes that “there are no signifying practices; *signification* should rather be understood as an integral element of social practices in general.” (p. 39).

Similarly, in terms of *interaction*, *communication* of meaning does not take place separately from *power* relations, or outside of *sanction*.

Structuration in the context of Operational Excellence Programs

By integrating structuralist and agentic perspectives, the theory of structuration provides a framework that can facilitate a better understanding of the interrelation between the management infrastructure, behavior and mindset as well as the operating system, which depict three main OPEX levers, according to (Drew et al., 2004). Yet, to date, the theory of structuration has received little attention in OPEX literature. Predominately, existing OPEX research adopts perspectives related to the study of socio-technical systems or to organizational culture (cf. chapter 2.1). While such perspectives are useful to highlight the importance of social-technical or cultural effects in OPEX programs, they do not provide guidance for studying the interrelation between structural and agentic aspects of OPEX programs. From a structuration perspective, however, such integrated considerations could be helpful for OPEX research on human behavior management for increased and sustained operational performance.

Based on the *duality of structure* concept, the theory of structuration provides a framework that can help put structural and behavioral aspects of OPEX programs in relation to each other. From a structuration perspective, the OPEX levers management infrastructure and MB represent aspects of *structure* respectively of *interaction*. The structuration theory can therefore enhance the understanding of interactions between these OPEX levers. Ultimately, this can help implement the interrelated technical and social OPEX systems in a more integrated way by enhancing the understanding of interactions between the levers of the social OPEX system.

To summarize, the theory of structuration can be viewed as a suitable theoretical grounding for the research problem of this dissertation. First, it integrates a structuralist perspective with an agentic perspective, which can help study the complex interrelations between the OPEX levers of the social OPEX system, in terms of management infrastructure, MB and ultimately SFB. In addition, it specifies relevant subdimensions of management infrastructure and MB by providing relevant subdimensions of *structure* and *interaction*, as depicted in *Figure 10*. Lastly, it can provide guidance for studying the relation between management infrastructure, behavior and the operating system in the context of OPEX programs holistically.

Implications from adopting a structuration perspective for OPEX research

Much like our research problem, the theory of structuration involves both behavioral and structural aspects. In the following, we elaborate on implications from adopting such a perspective for our research context.

As a leading theorem, (Giddens, 1979) deduces that “every social actor knows a great deal about the conditions of reproduction of the society of which he or she is a member.” (p. 5). In other words, not only *structure*, but also organizational members through their awareness of the structural aspects influence the reproduction of organizational behavior. *Structure* and *interaction* are therefore viewed as both the medium and the outcome in the process of structuration. In terms of studying the reproduction of SFB as part of our research, the theorem suggests that the role of the management infrastructure should not be interpreted apart from MB and SFB.

While existing OPEX literature acknowledges the role of management infrastructure and MB as a medium for impacting SFB, it takes interactions between structural and behavioral aspects only partially into account. Specifically, it rarely admits interaction effects between MB, SFB and management infrastructure into consideration. As a result, effects of SFB on management infrastructure or integrated effects of MB and management infrastructure on SFB are inadequately taken into consideration. For example, employee behavior is often viewed as an intermediate outcome of changes in the management infrastructure. Yet, reverse effects of SFB on the management infrastructure that may in turn have behavioral implications are typically not in the focus. Similarly, interactions between management infrastructure and MB are typically neglected, even though the role of MB for directing SFB is emphasized in OPEX research.

By neglecting the interdependencies between *structure* and *interaction* in the process of structuration, OPEX literature potentially oversimplifies the relation between management infrastructure and organizational behavior. From a structuration perspective, this can result in misleading conclusions regarding their individual role for OPEX. Possible misconceptions can include an over or underestimation of effects from individual structural or behavioral aspects or an attribution of intended or unintended effects to incorrect root causes. To highlight the importance of considering both structural and behavioral aspects when studying social interaction, (Giddens, 1979) points to the role of unintended consequences and routinization for the reproduction of social *interaction* and organizational change. Examples of unintended consequences highlighted in literatures that are of relevance in the context of OPEX programs include selective attention and illusion of control (Franco-Santos & Otley, 2018), inertia and

disempowerment (Bititci, 2015), reduction of intrinsic motivation and employee engagement (Sitkin et al., 2010), excessive bureaucracy (Liker, 2004), or lack of learning and innovation capabilities (Adler & Borys, 1996).

We believe that OPEX research could benefit from adopting a structuration perspective. The three OPEX levers affect an organization's OPEX capabilities through complex interaction, as emphasized in OPEX literature. Following the concept of *duality of structure*, the theory of structuration could facilitate a more nuanced investigation of the role of MB and management infrastructure as both medium and outcome in the process of impacting SFB. Specifically, it could help relate management infrastructure, MB and SFB to each other in the context of OPEX programs.

Lastly, While the theory of structuration can be applied in a broad range of contexts to understand the relation between organizational change and social reproduction, (Giddens, 1979) points out that “there is little point in looking for an overall theory of stability and change in social systems, since the conditions of social reproduction vary so widely between different types of society” (p. 215). All theoretical implications derived from applying the theory of structuration in this research will, therefore, be considered in first instance specific to our respective context.

3.2 Research Framework

In order to derive a research framework for addressing the research problem, we draw on the three OPEX levers that are proposed by (Drew et al., 2004)¹⁰ and put them into relation with organizational performance. For this purpose, we first define operational performance as a suitable measure of organizational performance. We further distinguish the three OPEX levers into operations-oriented and people-oriented levers, by drawing existing OPEX research, such as (Shah & Ward, 2007), that views OPEX programs as socio-technical systems. We then put the people-oriented and the operations-oriented OPEX levers in relation with operational performance, based on the structuration theory.

According to existing OPEX literature, manufacturing firms ultimately look to “gain respectively sustain competitive advantage” when implementing OPEX programs. While the specific operationalization of competitive advantage differs in OPEX literature, it is often measured in terms of performance.

¹⁰ Management infrastructure, management behavior and mindset, as well as operating system.

The operating system represents an operations-oriented OPEX lever. Since it can directly influence operational performance, it depicts the independent variable in the developed research framework. Conversely, operational performance is viewed as the dependent variable in the research framework.

Based on the existing OPEX literature, management infrastructure as well as behavior and mindset are viewed as people-oriented OPEX levers. Since this research seeks to study the role that the management plays for impacting SFB in OPEX programs, we distinguish between management infrastructure, MB and SFB in the research framework. Both management infrastructure and MB are viewed as affecting the relation between the operating system and operational performance relationship, by influencing SFB. Consequently, both are considered potential moderating variables of the operating system-performance relationship in our research framework. Drawing on (Giddens, 1979) theory of structuration, we further draft the relation between management infrastructure and MB as an interaction, in which the one is involved in the reproduction of the other, and vice versa.

Finally, as emphasized in chapter 2.1, the effectiveness of the OPEX operating system depends heavily on the involvement and participation of every organizational member. Some of the reasoning behind it includes that OPEX practices for enhancing the OPEX operating system only contribute to enhanced performance if the workforce adopts them. In other words, when employees are not continuously engaged in OPEX practices, these practices do not contribute to reducing waste and, therefore, do not lead to increased performance. In the context of this research, employee behavior can therefore be viewed as a performance mediator.

Figure 11 shows the research framework that will guide this study in addressing the identified research gap. The framework provides several advantages over perspectives that solely distinguish between social and technical levers. First, by drawing on (Drew et al., 2004) as well as literatures that emphasize socio-technical system perspectives, such as (Shah & Ward, 2007), it puts the people-oriented OPEX levers management infrastructure and MB in relation with the operating system as the operations-oriented lever. This allows relating both to operational performance. Thus far, only few empirical OPEX research has attempted to put OPEX levers in relation to each other from such an integrated and holistic perspective. Notable exceptions include (Bortolotti, Boscari et al., 2015; Cua et al., 2001; Hadid & Mansouri, 2014). Second, it underlines the importance of MB and management infrastructure as key levers of the social OPEX subsystem, by integrating the practitioner oriented conceptualization of OPEX levers by (Drew et al., 2004) with the theoretical perspective on human behavior management by

(Giddens, 1979). Third, by drawing on the concept of *duality of structure* as proposed by (Giddens, 1979), it establishes a link between the two levers management infrastructure and MB. Finally, admitting contextual factors into the analysis can help to control for circumstantial influences, which can improve the understanding of the relationships between the other variables of our research framework. In summary, by establishing a more nuanced link between different dimensions of OPEX programs and performance, the proposed framework helps address the identified research problem in order to provide researchers and practitioners with valuable guidance for implementing OPEX.

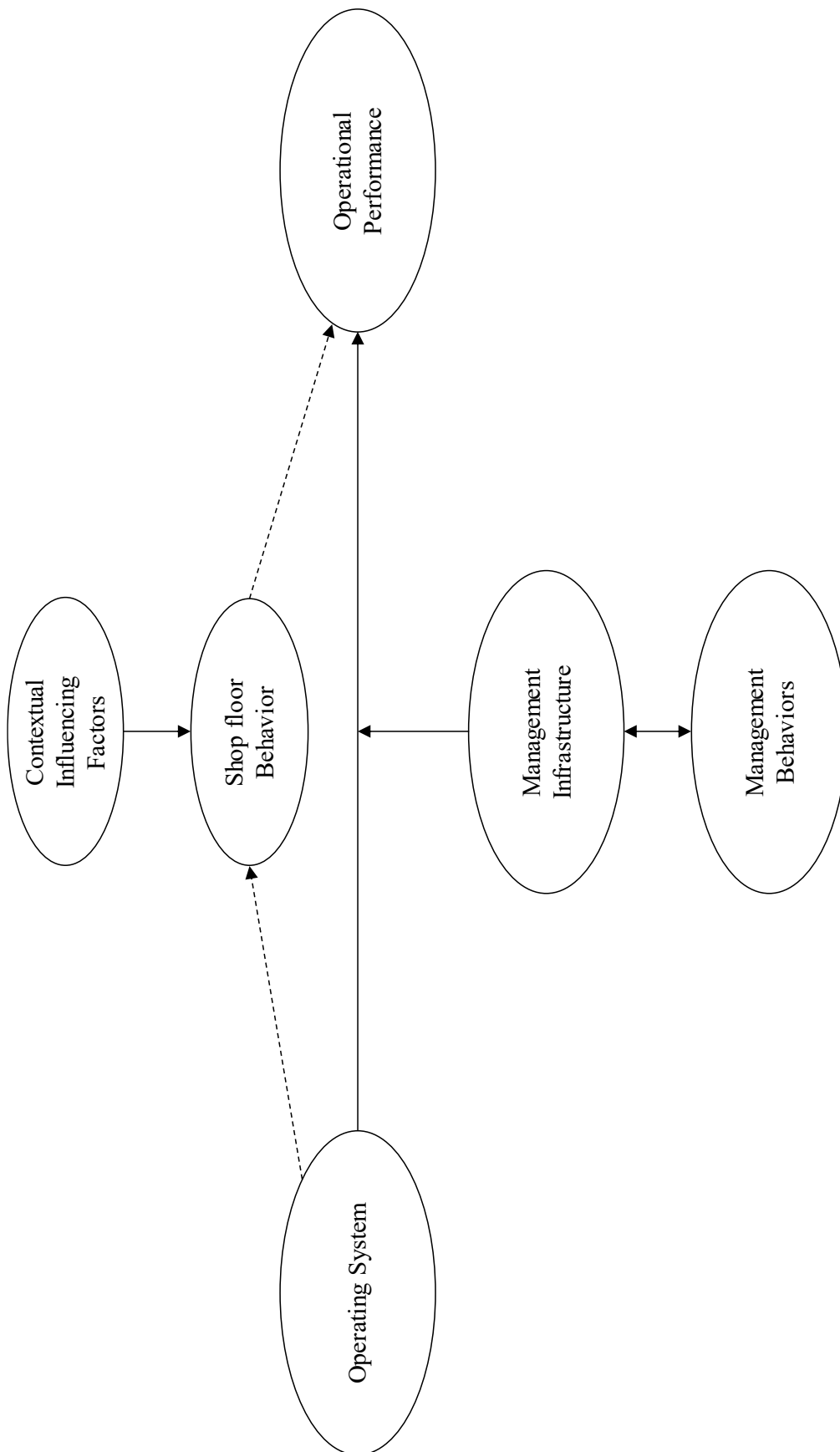


Figure 11: Research framework

3.3 Research Model

In the previous chapter, we drew on both OPEX literature and the theory of structuration to conceptually put SFB in relation with the management system and operational performance. In the following, we derive both a research model that can be empirically tested as well as respective research hypotheses.

As reflected by our research framework, we intend to study the effects that OPEX managers can have on the relation between the OPEX operating system and performance by influencing human behavior. Since the OPEX operating systems are reflected by the implementation of operations-oriented OPEX practices and identifying OPEX practices is not a trivial task (Hadid & Mansouri, 2014), we conceptualize these practices in a first step. In a second step, we present the results from reviewing existing literature on the research framework components in order to derive the research hypotheses.

Conceptualization of operations-oriented OPEX practices

Adopting a structuration perspective in the context of OPEX programs highlights a conceptual difference in the way that (Giddens, 1979) uses the term ‘practice’ as in ‘social practices’, to the way it is used in OPEX literature. In OPEX research, OPEX practices commonly refer to the organizational efforts made to implement and sustain OPEX (Cua et al., 2001). In this context, the implementation levels of OPEX practices are often used to evaluate the degree to which OPEX is implemented (Shah & Ward, 2003). In literature, OPEX practices therefore refer, more generally, to the means applied as part of OPEX transformations. In contrast, (Giddens, 1979) uses the term ‘practice’ specifically to refer to *interaction* in terms of actual social behavior.

In this research, we follow the more colloquial understanding of the term ‘practice’. Following (Schatzki, 2012), operations-oriented OPEX practices can therefore be viewed as the organized constellation of activities aimed at fulfilling the purpose of the OPEX operating system. Accordingly, OPEX can be viewed as the successful adoption of operations-oriented OPEX practices on the one hand and people-oriented OPEX practices on the other hand.

Contextual Operational Excellence barriers

The OPEX literature points to a range of potential barriers that can hinder OPEX by affecting the adoption of OPEX practices. From a socio-technical perspective, these barriers cannot merely be categorized into those that affect the social, and those that

affect the technical OPEX subsystem. Instead, many of these barriers, concern both subsystems in some way, due to complex socio-technical interaction.

Barriers that affect the social subsystem can involve either the employees or the management of an organization. An exemplary potential barrier that involves the management of OPEX programs includes idealistic or dogmatic views of leadership, without in-depth knowledge of the overall situation of the system (Zipkin, 1991). On the other hand, a potential OPEX barrier that involves the employees can be hasty changes without “dealing with the reasons for the supposed waste” (Browning & Heath, 2009, p. 41).

For this research, we are interested only in contextual barriers that can affect the social subsystem of pharmaceutical manufacturers in ways that can also impact SFB. Thus, potential barriers that do not affect the social subsystem are not further considered in the following. To further narrow down the scope of relevant barriers, we define contextual factors as those factors that can hardly or not at all be changed by management, and we only study respective barriers as part of the empirical study.

In order to identify relevant categories of contextual barriers, this research draws on an extensive and recent literature review on OPEX barriers that was conducted by (Zhang et al., 2017). Using an interpretive ranking process and a group discussion technique that involved OPEX experts, the authors suggest that OPEX barriers can be sorted into ten categories. Based on these categories, five categories of contextual barriers are derived that relate to the management of human behavior and that meet the criteria defined above (cf. *Table 9*).

Table 9: Barriers for OPEX implementation, adapted from (Zhang et al., 2017)

Author	1	2	3	4	5	6	7	8	9	10
OPEX Barriers ¹¹										
<i>Knowledge (KN)</i>										
Lack of training	•	•	•	•	•					
Insufficient understanding of benefits		•	•			•	•	•		
Lack of OPEX understanding	•						•		•	
Lack of implementation know-how ¹²	•		•			•		•		
Resistance to practice 'learn and see'			•							
<i>Conflicts (CO)</i>										
Conflicts with other initiatives ¹³	•	•			•					
Frequent changes in design		•	•							•
Apathy of consultants	•	•			•					
Lack of cooperation from suppliers		•			•					•
Heterogeneous environments	•	•								
<i>Resource (RES)</i>										
Insufficient cost	•				•	•	•		•	
Insufficient internal or external funding		•				•		•		•
Lack of time or labor resources	•							•		
Lack of innovative ideas	•									
<i>Employee & Culture (EC)</i>										
Employee attitude or resistance to change	•	•	•		•	•	•	•		
Lack of empowerment					•					
Lack of OPEX behavior				•						
Cultural issues	•		•		•	•		•		
Past experiences/backsliding		•			•			•		
<i>Financial outcome (FO)</i>										
No direct financial advantage	•									

(1) (R. Kumar & Kumar, 2014), (2) (Sharma et al., 2014), (3) (A. Kumar, 2014), (4) (Cheah et al., 2012), (5) (Jadhav et al., 2014), (6) (Bhasin, 2012), (7) (Nordin et al., 2010), (8) (Wong et al., 2009), (9) (Staudacher & Tantardini, 2007), (10) (B. Singh et al., 2010)

The first barrier category that is of relevance for this research is *knowledge*. Lack of *knowledge* can concern different aspects of OPEX programs and can therefore affect OPEX in different ways. one example depicts *insufficient understanding of benefits* from OPEX, as shown in Table 9. It can hinder the alignment of all organizational efforts towards OPEX and can therefore act as a barrier. In addition to showing *insufficient understanding of benefits*, companies can also lack understanding of the underlying

¹¹ The categories 'employee' and 'culture' from Zhang et al. (2017) were merged into one category *employee & culture*. The barrier 'backsliding' from category 'past experience' was included therein, since it is closely related to both of the underlying categories 'employee' and 'culture'.

¹² Zhang et al. (2017) additionally list lack of skills of workforce, supervisor and senior managers as well as a lack of methodology as barriers, which are all included in one category named *lack of implementation know-how*.

¹³ The barrier 'viewed as flavor of the month' from Zhang et al. (2017) can be viewed as a *conflict with other initiatives*. It is, therefore, included in that respective category.

OPEX philosophy and objectives, respectively they can lack the know-how that is necessary for implementing OPEX. To illustrate, the authors emphasize that OPEX involves a variety of tools and techniques and conversely require diverse skills and methodological approaches. Therefore, lack of OPEX understanding as well as lack of implementation know-how are considered separate potential OPEX barriers. On the basis of the arguments outlined above, (Zhang et al., 2017) identify lack of training of employees and managers as a main reason why OPEX programs fail. Since the pharmaceutical manufacturing environment can place industry-specific demands on managers and employees, for example in terms of training or implementation know-how, we hypothesize the following:

H1a: Knowledge-related barriers for OPEX behavior exist that are pharma specific.

A second category of contextual barriers depicts *conflicts*. Based on their literature review, (Zhang et al., 2017) emphasize the risk of conflicting initiatives. According to the authors, examples of unwanted consequences include confused, discouraged or even disengaged employees. The management approaches that are applied for OPEX implementation should therefore have a limited risk of creating such conflicts. Other potential barriers that can hinder OPEX behavior include frequent design changes, lack of customization of OPEX programs to the manufacturing environment or lack of support from external partners, such as suppliers or consultants. As the presence of conflicts depends on the aspired state is, which can vary based on circumstance and context, we hypothesize for the category *conflicts*:

H1b: Conflict-related barriers for OPEX behavior exist that are pharma specific.

As OPEX programs are aimed achieving complex organizational change involving both the social and the technical subsystem, (Zhang et al., 2017) suggest that they can be resource demanding. *Resource* can therefore be viewed as a third category of contextual barriers for OPEX behavior. In the literature review, *resource* barriers include lack of funding, lack of time or lack of labor. To illustrate, for example, the importance of funding or time for influencing OPEX behavior, one can draw on the critical role that training can play, as outlined above. The authors further identify lack of generation of innovative ideas as another potential barrier for OPEX behavior, since OPEX relies on continuous learning and improvement. To conclude, we hypothesize:

H1c: *Resource-related barriers for OPEX behavior exist that are pharma specific.*

Employee & Culture depicts the fourth category of contextual barriers. As (Jadhav et al., 2014) point out, OPEX relies on employees that are engaged in decision-making and problem solving. Unwanted consequences of a lack of employee engagement can include dysfunctional communication and collaboration and more broadly non-OPEX behaviors (Cheah et al., 2012). Contextual factors that cause employees to be reluctant to engage in OPEX activities, therefore, depict critical OPEX barriers.

Overall, (Zhang et al., 2017) identify both cultural issues and issues of individual employees as potential barriers for OPEX behavior. According to the authors, potential barriers include employee attitude or even resistance to change, lack of empowerment, cultural issues, or counterproductive past experiences. This is in line, on the one hand, with (Wong et al., 2009), who suggest that failure to develop an adequate OPEX culture can hinder OPEX behavior. On the other hand, this corresponds to (A. Kumar, 2014), who points out that, for example, demotivating employee expectations or exerted organizational pressure can divert employees from adopting OPEX behaviors. Such expectations can include fear of disadvantageous effects from engaging in cost and waste reduction activities as part of OPEX programs, including making their jobs obsolete (Bhasin, 2012). Recognizing that organizational culture as well as employee attitude towards OPEX can be dependent on contextual factors, we hypothesize:

H1d: *Employee & Culture-related barriers for OPEX behavior exist that are pharma specific.*

Finally, *financial outcome* depicts the sixth category of contextual barriers. It refers to the importance of adequately understanding the benefits from OPEX. According to (Staudacher & Tantardini, 2007), if financial outcomes of the available OPEX levers are not properly understood, required resources cannot be justified. Hence, a lack of funding in one or many of the categories depicted in *Table 9* can cause unintended consequences for OPEX behavior. Analogously to an a priori lack of understanding of financial benefits, an a posteriori lack of recognized financial advantage can hinder OPEX behavior. It therefore represents a critical barrier for two reasons. On the one hand, failure to show beneficial financial outcomes can undermine the management's ability to justify funding for OPEX programs. At the same time, as (Zhang et al., 2017) point out, measuring the financial outcome of different aspects of OPEX programs is inherently challenging, since some of its benefits may be more intangible, but nevertheless indirectly contribute to financial performance. Examples include safety

improvements or higher employee engagement. For the category *financial outcome*, we therefore hypothesize:

H1e: *Financial outcome-related barriers for OPEX behavior exist that are pharma specific.*

Management control dimensions in OPEX programs

To narrow down the scope of relevant facets of the management infrastructure for impacting shop floor behavior, this dissertation builds on the MC literature. As introduced earlier, this stream of literature provides various MC constructs that managers can put in place to guide worker behavior. By directing behavior, these constructs can affect the degree to which an organization achieves its strategic goals (Anthony, 1965). In the context of OPEX programs, where program component such as JIT, TQM and TPM can be viewed as strategic initiatives, this stream of literature serves well for identifying means that support OPEX by impacting shop floor behavior.

In order to identify relevant MC dimensions, this dissertation further draws on OPEX literature, MC literature, as well as literature at the intersection of both research streams, as illustrated in *Figure 12*. First, it OPEX literature on MC is reviewed to identify a first set of relevant MC dimensions in OPEX programs. Since the existing OPEX literature on MC makes no claim of comprehensiveness in terms of the studied MC dimensions, no comprehensive overview of relevant MC dimensions exists in OPEX programs. In a second step, the identified MC dimensions are therefore reflected based on the MC constructs outlined in chapter 2.2. Finally, this research draws on OPEX literature to reflect whether the identified MC dimensions depict common components of OPEX programs.

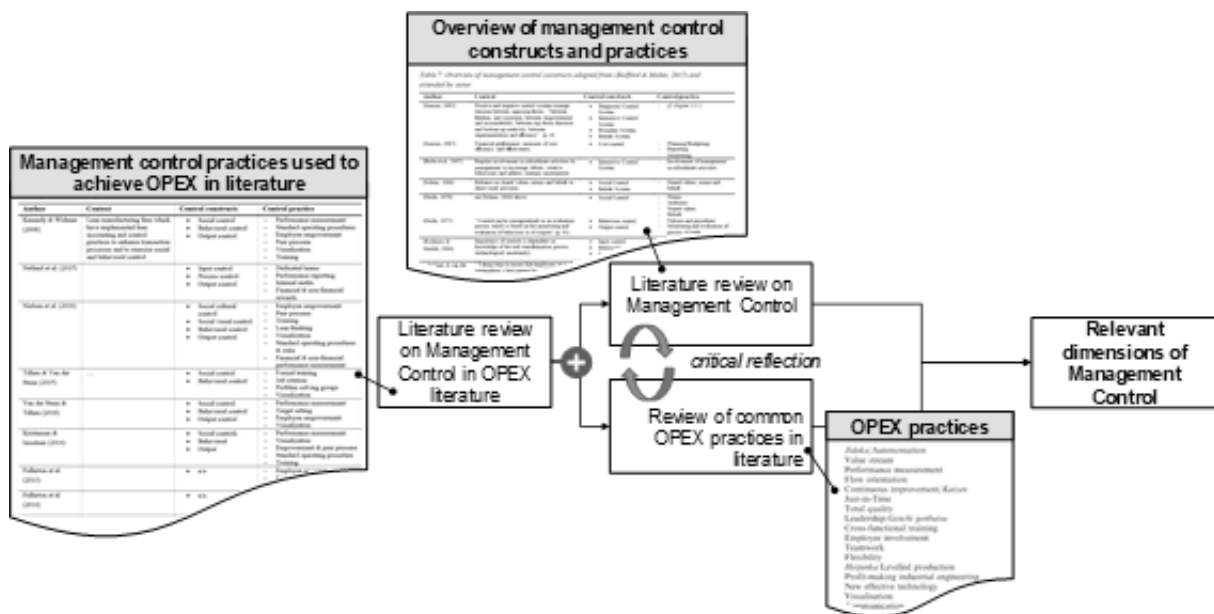


Figure 12: Identification of relevant MC dimensions based on review of two research streams

OPEX literature on MC is limited to just a few studies that are depicted in *Table 10*. The respective literature commonly distinguishes MC into the three categories social control, behavioral control, and output control (cf. chapter 2.2.2). Input control can be understood as those controls that are applied to direct behavior on the input side. It can be exerted, for instance, through employee training. Process control, on the other hand, guide the behavior during the process. Examples include standard operating procedures, which ensure that tasks are performed to specification. Finally, output control influence employee behavior at the output of a process and can be achieved, for example, through performance measurement. Notable exceptions in OPEX literature that do not distinguish between input, process and output control include on the one hand (Fullerton et al., 2013, 2014), who don't explicitly categorize different types of MC. Another example depicts (Netland et al., 2015), who follow (Merchant & van der Stede, 2012) and distinguish instead between input control, process control, and output control.

Table 10: Management Control in Operational Excellence literatures

Author	Control Constructs	Control Mechanisms
(Netland et al., 2015)	• Input control • Process control • Output control	- Dedicated teams - Performance reporting - Internal audits - Financial & non-financial rewards
(Kennedy & Widener, 2008)	• Social Control • Behavioral control • Output control	- Performance measurement - Standard operating procedures - Employee empowerment - Peer pressure - Visualization - Training
(Fullerton et al., 2013)	N/A	- Employee empowerment - Visual performance measures
(Fullerton et al., 2014)	N/A	- Visual performance measures
(Tillema & van der Steen, 2015)	• Social control • Behavioral control	- Formal training - Job rotation - Problem solving groups - Visualization
(van der Steen & Tillema, 2018)	• Social control • Behavioral control • Output control	- Performance measurement - Target setting - Employee empowerment - Visualization
(Kristensen & Israelsen, 2014)	• Social Control • Behavioral control • Output control	- Performance measurement - Visualization - Employee empowerment & peer pressure - Standard operating procedures - Training
(Nielsen et al., 2018)	• Social cultural control • Social visual control • Behavioral control • Output control	- Employee empowerment - Peer pressure - Training - Lean thinking - Visualization - Standard operating procedures & rules - Financial & non-financial performance measurement

Based on the review of the studies above, the MC mechanisms that have already been recognized in OPEX literature are identified. By comparing the MC mechanisms against the common OPEX practices presented in chapter 2.1, MC dimensions that depict core components of OPEX programs are derived. In this process, the mechanisms peer pressure, internal audits and financial as well as non-financial rewards are excluded since they do not represent common OPEX practices. At the same time, no additional MC mechanisms were derived from MC literature that represent common OPEX

program components. The remaining list of MC mechanisms are then combined as appropriate and clustered into six distinct MC dimensions. To cross-check the results, the identified MC dimensions that are relevant in OPEX programs are mapped against the five MC categories proposed by (Malmi & Brown, 2008) (cf. chapter 2.2). The final set of MC dimensions that are obtained as a result include *training*, *employee empowerment*, *goal setting*, *standardized work*, *visualization* and *performance measurement* (cf. Table 11).

Table 11: Relevant Management Control dimensions in OPEX programs

Management Control dimension	Description
Planning	
Goal Setting	The degree to which site and corporate objectives and goals are clearly communicated and linked to individual objectives.
Cybernetic controls	
Performance measurement	The degree to which process performance is continuously measured.
Visualization	The degree to which performance objectives and status, as well as workplace information are easily accessible and visible.
Administrative controls	
Standardized work	The degree to which standardized work is emphasized and roll-out throughout the organization.
Training	The degree to which the organization is dedicated to employee development to increase worker flexibility and capability.
Cultural controls	
Employee empowerment	The degree to which employees are enabled to engage in continuous improvement through cross-functional teamwork and implementation of OPEX tools and methods.

Management Behavior as a Key OPEX Lever

As outlined above, as a leading theorem the theory of structuration suggests that both structural aspects as well as organizational members influence the conditions the reproduce behavior in social systems. In their dual capacity as both influencers of structural aspects of the management system and as agents, managers therefore play a crucial role for impacting organizational behavior.

The role of MB for supporting OPEX has only recently gained interest in OPEX research. Recent contributions include both exploratory studies as well as confirmatory research that are aimed at identifying effective MBs in OPEX programs.

For example, (van Dun et al., 2017) identify 19 MBs in an exploratory study that are then clustered into the four groups task-oriented (e.g. task-monitoring), relations-oriented (e.g. active listening), change-oriented (e.g. asking for ideas) and so-called counterproductive behaviors (e.g. showing disinterest). The authors find that managers engage more often in relations-oriented behaviors to implement OPEX and less in task-oriented behaviors or in counterproductive behaviors (Tortorella et al., 2017). (Netland, 2016) identifies a generic list of 24 critical OPEX success factors, which also include MBs, such as personal participation, following up, or finding and sharing best practices.

Studies that validate the hypothesized effects of certain MBs on OPEX implementation include (Camuffo & Gerli, 2018). Using regression analysis and non-parametric hypothesis testing, the authors identify MBs that support OPEX by complementing the adoption of OPEX practices. Notable behaviors that are believed to support OPEX include working collaboratively, developing standards, or frequently evaluating performance. The authors further suggest a need to adopt MBs to circumstance, based on findings showing that more advanced OPEX systems are associated with different subsets of these behaviors. Finally, empirical research that validates the potentially beneficial effects that MBs can have on OPEX include (van Assen, 2018). The author finds that active steering can support OPEX in the context of process improvements.

The existing OPEX literature shows a consensus regarding the importance of MB for OPEX. Yet, exploratory research on the specific behaviors that support OPEX in different contexts is still limited. Research has therefore suggested a need for situational approaches to supporting OPEX with MBs (Camuffo & Gerli, 2018), which suggest that different behaviors may be beneficial in different contexts, such as the pharmaceutical manufacturing environment. Since behavioral and structural management aspects are furthermore viewed as interacting, six hypotheses are derived for a subsequent empirical evaluation, each one being linked to one of the six previously identified relevant MC dimensions:

***H2a:** Management behaviors exist that can support employee empowerment in the context of pharmaceutical OPEX programs.*

***H2b:** Management behaviors exist that can support training in the context of pharmaceutical OPEX programs.*

***H2c:** Management behaviors exist that can support goal setting in the context of pharmaceutical OPEX programs.*

***H2d:** Management behaviors exist that can support standardized work in the context of pharmaceutical OPEX programs.*

***H2e:** Management behaviors exist that can support visualization in the context of pharmaceutical OPEX programs.*

***H2f:** Management behaviors exist that can support performance measurement in the context of pharmaceutical OPEX programs.*

Performance Effects

Operations-oriented OPEX practices

The consensus in OPEX literature is that OPEX programs are generally beneficial for operational performance. Yet, empirical research on the link between OPEX practices and operational performance have found mixed results. A meta study by (Mackelprang & Nair, 2010) emphasize that previous studies on the respective relationship have found ambiguous results. A study by (Negrão et al., 2016) recently confirmed the mixed results. On the one hand, (Cua et al., 2001; Netland et al., 2015; Shah & Ward, 2003) found a positive relationship between OPEX practice implementation and performance. On the other hand, scholars such as (Bortolotti et al., 2013; Z. Chen & Tan, 2013) did either not find a significant positive relationship or they even found a negative one.

In the light of mixed performance results from OPE programs, researchers have suggested that these may be explained by a lack of consideration of contextual factors, on the one hand, and interaction effects between the components of OPEX programs, on the other hand (Mackelprang & Nair, 2010). While previous research has already identified the potential relevance of contextual factors for OPEX, one research question that arises from this is in what contexts OPEX implementation is indeed associated with increased performance.

Thus far, the OPEX practice-performance relationship has only been studied sparsely in the context of pharmaceutical manufacturing. Predominately, respective research focuses on discrete manufacturing to the neglect of the process manufacturing (Abdulmalek et al., 2006), such as pharmaceutical manufacturing. Notable exceptions that investigate performance effects of OPEX in pharmaceutical manufacturing include (Friedli, 2010; Friedli et al., 2013; Friedli et al., 2018) who emphasize the potential of OPEX and who provide empirical evidence for positive effects from OPEX. Other studies include (Gebauer et al., 2009), who suggest a positive relationship between

implementation of TPM, TQM, JIT, HRM and operational performance and (Nenni et al., 2014), who found a positive relation between the implementation of the OPEX component pull-production and efficiency.

The differences between pharmaceutical manufacturing and discrete manufacturing can change the way OPEX practices can be deployed and thus their effects on firm performance (Lyons et al., 2013). In terms of the former, (Shah & Ward, 2003) provide empirical evidence for significant differences in OPEX implementation between discrete manufacturing firms and process manufacturing firms. Likewise, (Friedli et al., 2013) note that OPEX implementation may have been delayed in pharmaceutical firms compared to discrete manufacturing firms due to the unique characteristics of the process industry. With regards to differences in performance effects, (Eroglu & Hofer, 2011) showed that also the OPEX practice-performance relationship varies between industries in terms of significance of effects of individual practices.

To conclude, existing research suggest that different contextual factors, such as industry, and manufacturing type, more specifically, can influence the adoption of OPEX practices. In addition, empirical evidence exists that they can also influence the relationship between OPEX practice implementation and firm performance. Finally, enough evidence exists that suggests that OPEX programs can also significantly increase operational performance in pharmaceutical manufacturing, despite potential differences between process and discrete manufacturing. We therefore hypothesize:

***H3:** The application of operations-oriented OPEX practices is positively associated with the operational performance of pharmaceutical manufacturing firms.*

Management Control

In the previous chapters it is theorized that MC, OPEX practices, and performance are interrelated. This view is based on a socio-technical system perspective on OPEX programs, which proposes that to increase operational performance, firms must optimize the technical and the social OPEX subsystem in conjunction. Conversely, increasing performance with OPEX programs would involve both the operations-oriented OPEX practices and relevant MC dimensions, since both represent relevant facets of the technical and the social OPEX subsystems.

While the existing OPEX literature provides initial evidence for an interrelation between MC and OPEX (cf. *Table 10*), less consensus exists regarding what facets of MC support or hinder OPEX. All relevant MC dimensions are commonly applied in OPEX programs to influence worker behavior, and all can therefore be viewed as facets

of the social OPEX subsystem. As such, they potentially support OPEX. However, they can potentially also lead to counterproductive consequences, as emphasized in the MC literature. Thus, to hypothesize about the relation between MC and performance in the context of OPEX programs, a closer look at potential effects of MC is helpful. The following section elaborates on the intended as well as unintended effects of the identified relevant MC dimensions in the context of OPEX programs.

Intended effects of management control in OPEX programs

First, OPEX literature supposes that *employee empowerment* benefits OPEX, since it heavily depends on worker participation at the expense of top-down control (van der Steen & Tillema, 2018). Providing employees with the means and autonomy that are necessary for participating in timely decision making and in improvement activities can make them more attentive and caring for implementing and sustaining OPEX (Fullerton et al., 2013). Furthermore, it can enable workers to engage in experimentation, which facilitates continuous improvement of key processes (Nielsen et al., 2018).

Second, *training* can positively impact OPEX, since OPEX demands a wide range of competencies from its employees. By building methodological expertise and by facilitating successful practice sharing, *training* can enable employees to perform various tasks related to OPEX more effectively and efficiently. Common facets of MC that are associated with *training* include cross-training, job rotation programs or problem solving in groups (Tillema & van der Steen, 2015). *Training* can further help motivate the workforce to engage in OPEX, for instance by increasing problem awareness or by equipping employees with adequate OPEX knowledge. It can therefore act as a mean not only for employee qualification, but also for employee engagement in OPEX.

Next, *goal setting* can support OPEX by defining a clear target state and by providing purpose and motivation. According to (Bortolotti, Boscari et al., 2015), *goal setting* facilitates the convergence of all organizational efforts towards a common strategic goal. Accordingly, by setting clear goals, misconceptions about targets or paying attention to the wrong things can be avoided (Bhamu & Sangwan, 2014). This is in line with (Malmi & Brown, 2008), who consider goal and action planning a core element of MC systems. Similarly, (Galeazzo et al., 2017) suggests that *goal setting* can facilitate organizational learning, since it focuses organizational attention. Finally, linking plant with employee objectives can lead to increased employee engagement in OPEX and can therefore reduce the risk of employee resistance to implementing OPEX (Lozeau et al., 2002).

Fourth, *standardized work* can affect OPEX positively by specifying how processes and procedures are to be performed. As a result, it can guide worker behavior in the process in a way that enables them to perform their tasks more efficiently. *Work standardization* can also serve as a baseline for continuous improvement in terms of SOPs that can be continuously updated to facilitate improvements (Nielsen et al., 2018). By formalizing current best practices, *standardized work* can not only contribute to higher levels of process quality, it can also support organization wide learning and improvement based on replication of formalized successful practices (Nelson & Winter, 1982). By capturing current work processes, *standardized work* therefore serves as a platform for human error reduction, process documentation and improvement planning, which can help structure the operations. Moreover, it can facilitate a more consistent application of OPEX practices across different teams that can eventually lead to better operational performance.

Fifth, *visualization* can support OPEX by facilitating visual feedback. Among others, it can be used to indicate deviations from defined standards, which in turn can help direct the attention of shop floor personnel to potential improvement areas (Liker, 2004). To illustrate, it can enable workers to continuously monitor the effectiveness of operational changes by providing visual feedback on current performance levels. Since OPEX programs involve regular organizational change, increased levels of transparency on performance levels can support the effective implementation of OPEX practices. Finally, it can help shop floor personnel understand how their work relates to other organizational areas, which can facilitate organizational learning and ultimately continuous improvement (Nielsen et al., 2018).

Lastly, *performance measurement* can have beneficial effects for OPEX by providing critical information on process status. As outlined in MC literature, facilitating transparency on process performance can enable better decisions and responding to situations more appropriately (Chenhall, 1997). It can also motivate workers to engage in OPEX, by providing a basis for identifying improvement opportunities (Fullerton & Wempe, 2009). Finally, access to relevant information is considered a success factor for strategy implementation (Early et al., 1989). From a perspective of OPEX programs as a strategic initiative, *performance measurement* could, for example, help focus organizational efforts on areas that promise significant performance improvement potential. In this context, it could provide workers with valuable guidance on what areas of production to target. *Table 12* summarized the derived intended effects of the relevant MC dimensions for OPEX.

Table 12: *Intended shop floor behaviors of relevant Management Control dimensions*

MC dimension	Purpose for OPEX	<i>Intended shop floor behavior (SFB)</i>						
		(1)	(2)	(3)	(4)	(5)	(6)	(7)
Employee Empowerment (EE)	Enable the work force to identify, analyze and address improvement opportunities for OPEX on their own.	•	•	•	•			
Training (TR)	Equip employees with sufficient OPEX knowledge to deploy relevant aspects of the OPEX program in desired ways.	•	•		•			
Goal Setting (GS)	Provide employees with a clear direction for continuous improvement that focuses their attention on a common goal and that is engaging.	•				•	•	•
Standardized work (STD)	Define currently best-known ways of working to facilitate stable processes as a basis for continuous improvement.	•					•	
Visualization (VIS)	Make target state and current process status visible to facilitate timely decision making.	•		•		•		•
Performance Measurement (PM)	Provide transparency on current performance levels to highlight existing gaps with improvement potential.	•	•					•

(1) Identifying improvement opportunities, (2) identifying root causes, (3) Timely and independent decision making, (4) Acting on improvement opportunities, (5) Highlighting issues that require escalation, (6) Adhering to standards, (7) Fact-based decision making

Unintended counterproductive effects

In contrast to the intended effects of the relevant MC dimensions for OPEX, their potential counterproductive effects have received little attention in OPEX literature. Predominately, the OPEX literature focuses on identifying and evaluating the benefits from OPEX program components to the neglect of their potential counterproductive effects. Failure to achieve the desired results are thereby usually explained by shortcomings in program execution, rather than by characteristics of the applied OPEX program components.

Despite the lack of focus on unintended effects in OPEX literature, MC literature recognizes that different facets of MC can also lead to a variety of counterproductive consequences. Except for *employee empowerment* and *training*, unintended consequences are emphasized in MC literature for all identified relevant MC dimensions.

First, potential unintended consequences related to *standardized work* include inertia and disempowerment (Bititci, 2015), reduction of motivation and employee engagement (Sitkin et al., 2010), excessive bureaucracy (Liker, 2004) and a lack of learning and innovation capabilities (Adler & Borys, 1996).

Next, in terms of *performance measurement* and *visualization*, scholars emphasize that providing employees with immediate feedback on performance can result in unintended consequences (Franco-Santos & Otley, 2018). In this context, the authors identify strategic behavior, selective attention, and information manipulation, illusion of control and transformation of social relationships as potential unintended consequences.

Finally, in terms of *goal setting*, the MC literature points to the challenge of disconnected company priorities, performance measures and improvement activities (Bititci, 2015; Evans & Jack, 2003). Specifically for the context of OPEX programs, (van der Steen & Tillema, 2018) find that the accounting based approaches to MC, namely measurement of financial goal achievement, status quo oriented goal setting, and top-down control are incompatible with the applied as part of OPEX programs. These include improvement-oriented goal setting, empowerment of local teams, lateral control based on cooperation, and holistic performance orientation. Counterproductive consequences of the accounting-based approaches include, among others, lack of adequate investment in improvement initiatives, difficulty to communicate OPEX benefits, neglect of interdependencies within value streams, and difficulty to eliminate wasteful corporate accounting tasks.

In conclusion, the six MC dimensions have the potential to affect OPEX implementation in both beneficial and disadvantageous ways. Yet, the OPEX literature

focuses primarily on their beneficial effects, despite the outlined risk of counterproductive effects. Further, there is a consensus in OPEX literature that these MC dimensions depict core elements of the social OPEX subsystem, which are essential for OPEX implementation. Since the OPEX literature has not produced empirical evidence for potential net disadvantageous effects of MC in OPEX programs, the following six hypotheses are derived:

***H4a:** Employee empowerment positively moderates the relationship between operations-oriented OPEX practices and operational performance.*

***H4b:** Training positively moderates the relationship between operations-oriented OPEX practices and operational performance.*

***H4c:** Goal setting positively moderates the relationship between operations-oriented OPEX practices and operational performance.*

***H4d:** Standardized work positively moderates the relationship between operations-oriented OPEX practices and operational performance.*

***H4e:** Visualization positively moderates the relationship between operations-oriented OPEX practices and operational performance.*

***H4f:** Performance measurement positively moderates the relationship between operations-oriented OPEX practices and operational performance.*

The research model that is depicted below shows the relation between the operations-oriented OPEX practices, MC and operational performance under consideration of contextual barriers, which will be tested in the subsequent chapters using a mixed-method approach.

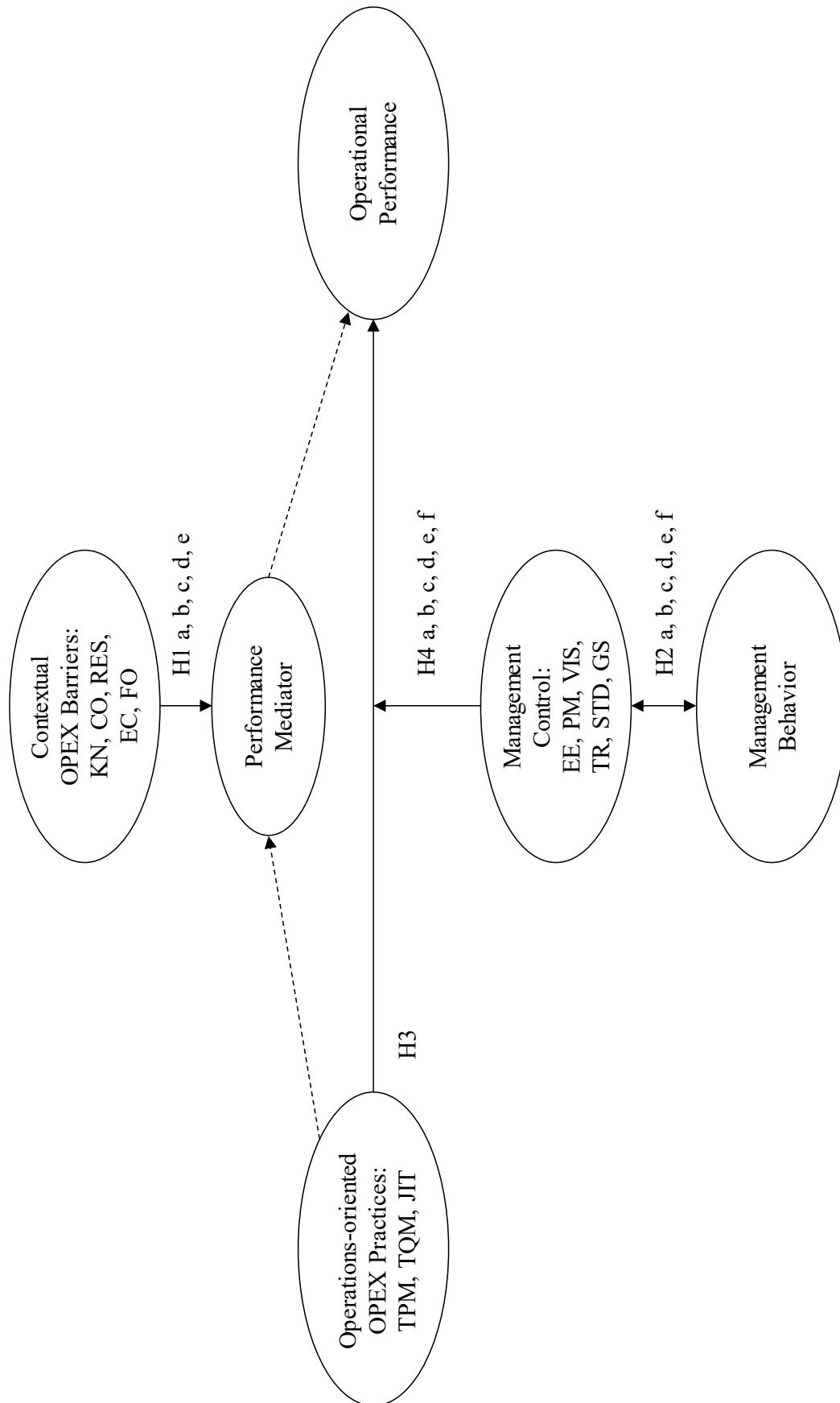


Figure 13: Research Model

4 Methodology

4.1 Research Setting

To empirically study the research problem, this study combines three research modes in a mixed-method approach. Combining different modes provides a sound empirical foundation that harnesses the unique access to empirical data from working in the Operational Excellence team at ITEM-HSG. *Figure 14* illustrates the research process for addressing the main research question.

This dissertation draws on empirical data on modern pharmaceutical OPEX programs that is derived from operating a global OPEX research group between 2018 and 2020 with OPEX experts from pharmaceutical manufacturers. The research group observations are then used to inform subsequent expert interviews to address the second and the third research question based on qualitative analyses. To address the last research question, this research finally draws on data from a global OPEX benchmarking study (University of St.Gallen OPEX benchmarking study) to quantitatively evaluate the role that MC plays in pharmaceutical OPEX programs. The data is used to study the interrelation between relevant MC dimensions as well as their potential moderating effects on the relation between operations-oriented OPEX practices and operational performance.

The intermediate results of this research were continuously reflected in an iterative learning process, based on empirics from conducting OPEX research and industry projects in the pharmaceutical industry. Notable access to empirics beyond research group work includes a three-year research project with the U.S. FDA on quality metrics in pharmaceutical manufacturing (Friedli et al., 2019), various benchmarking projects with pharmaceutical manufacturers in Europe, Asia and the U.S., and industry projects with leading pharmaceutical manufacturers on enhancing their OPEX programs.

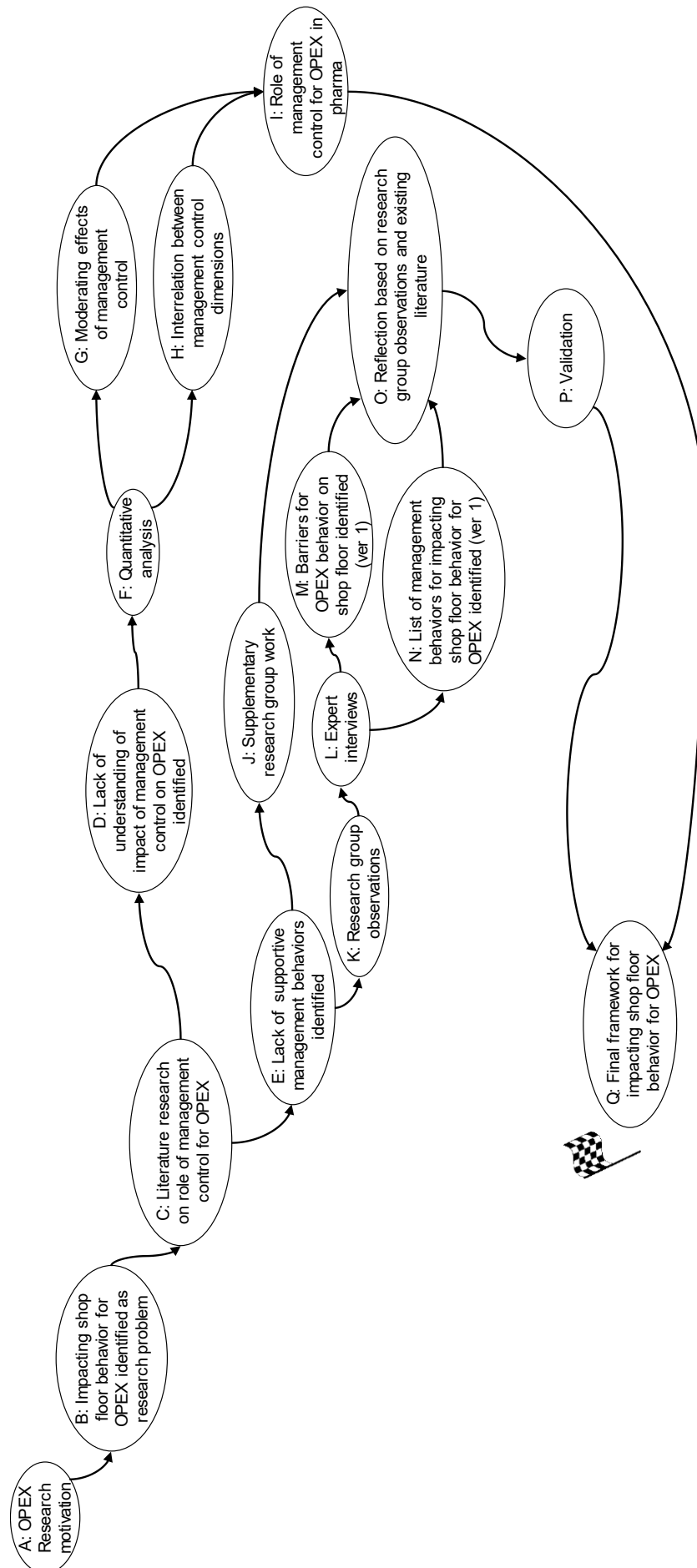


Figure 14: Overview of Research Process

4.2 Qualitative Analysis

4.2.1 Research Group Work

Group Set-up

The OPEX research group at the ITEM-HSG depicts a global exchange platform for OPEX experts from pharmaceutical manufacturers and academia. In the time between 2018 and 2020, four global meetings were conducted each year across the U.S. and Europe. In 2020, the meetings took place in a virtual mode, due to travel restrictions in connection with the global COVID-19 pandemic.

Over the course of the three years, a total of twelve two-day research group meetings were conducted, involving more than 40 representatives (*Appendix A*) from corporate OPEX roles of ten pharmaceutical companies (*Appendix B*). The ten companies define the scope of the qualitative analysis as part of this research. They represent pharmaceutical manufacturers of different sizes, regions, company type (e.g. generics manufacturer or patented drug manufacturer) and are headquartered in Europe, the U.S. or Asia. The company sizes, in terms of number of employees, range from 5.000 to more than 100.000. In terms of number of production sites they range from single-site companies to those with a production network of up to 60 production sites. The data sample can therefore be viewed as homogenous in terms of the firm's affiliation to the pharmaceutical manufacturing sector, and as heterogenous in terms of further context factors, such as company sizes, product type, region, OPEX program history. Since this research focuses on studying impacting SFB in pharmaceutical manufacturing, this industry specific data sample provides a solid basis for the qualitative analysis as part of this dissertation.

During the twelve research group meetings, detailed information on the architectures of the ten pharmaceutical OPEX programs, as well as on the reasons behind different design choices were obtained. The collected data therefore allows for in-depth insights into the operationalization of relevant OPEX program components for this research. Notable collected data includes, among others, corporate documents on approaches to human behavior management as part of the OPEX programs, including intended management behaviors, management standard work or approaches to OPEX capability building. The obtained data thus provides detailed insights into the current state of the social subsystems of modern pharmaceutical OPEX programs. Among others, these insights form the basis for studying the ways in which the six MC dimensions are applied in practice in the studied firms.

To obtain the empirical data, each company was asked during the group meetings to present their OPEX programs, including program history, main objectives, key challenges, as well as an outlook on planned improvements. For each meeting, the companies were further asked to prepare input presentations on selected OPEX topics, such as the OPEX management system. Further empirical evidence was generated through workshop sessions and visits of the plants of the research group companies.

Workshops

Research group workshops that were conducted between 2019 and 2020 are used to inform the identification of supportive management behaviors in expert interviews (*Appendix C*). The workshops were conducted as part of a group exchange on the topics *leadership & behavior* (2019) and *management behavior & leader standard work* (2020), which were defined by the participating companies as priority topics in 2019 and 2020. As part of the workshops, the research group was asked to brainstorm successful management behaviors that support the relevant MC dimensions. The group was also asked, more generally, to identify successful management practices for directing worker behavior and unintended consequences connected to these practices.

4.2.2 Expert Interviews

As part of the qualitative research, semi-structured interviews were conducted with subject matter experts from eight of the ten research group companies. The interviewed companies were pre-selected based on research group involvement between 2018 and 2020 to ensure access to comprehensive documentation of their OPEX programs. The final set of interviewees was then determined based on voluntary participation of representatives from the research group companies. To identify volunteers, the research group platform was utilized in two ways. On the one hand, by directly reaching out to company representatives at meetings, and on the other hand by reaching out to the main contact of each company with a request to identify suitable company representatives. The interviewees therefore work as OPEX and quality executives at the research group companies. In addition, interviews with two advisors from the pharmaceutical industry were conducted to obtain an external view that is independent from specific OPEX programs. Each interview was between 60-90 minutes.

Interviews were conducted, on the one hand, to identify relevant barriers for impacting SFB and to get a detailed understanding of how the six MC dimensions are applied. As result of these interviews, a set of contextual barriers for impacting SFB

with OPEX programs is obtained. The questionnaire that guided these semi-structured interviews is attached in *Appendix D*.

Overview of Questionnaire Structure

Barriers for Directing Shop Floor Behavior

Chapters	Sub-Topics
1 - Corporate approach to OPEX implementation	- General information - Corporate OPEX approach - Key challenges
2 - Application of management control to direct OPEX behavior	- Primary means to control and support OPEX behavior - Promoting or constraining beneficial or disadvantageous behavior
3 - Effect of management control	- Challenges & perceived benefits - Intended effects of management control dimensions
4 - Barriers for directing OPEX behavior	- Directing OPEX behavior in pharmaceutical manufacturing in general - Directing OPEX behavior with relevant management control specifically
5 - Miscellaneous	- Separation of quality and OPEX organization - Incentives and motivation - Focus of performance management system - Adjustment of management approaches to circumstance

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Figure 15: Structure of interview guide for identifying relevant barriers

Additional interviews were conducted using a questionnaire dedicated to management behaviors (*Appendix E*), to develop a detailed understanding of what management behaviors are intended for impacting SFB as part of the studied OPEX programs and why they are supportive. As a result of these interviews and informed by the research group work, a comprehensive list of supportive management behaviors for impacting SFB is obtained.

Overview of Questionnaire Structure

Supportive Management Behaviors

Chapters	Sub-Topics
1 - Context of leadership in current OPEX program	- Corporate OPEX approach - Key challenges
2 - Role of management behaviors in your OPEX program	- Role of management behaviors - Common undesired management behaviors in your organization
3 - Desired/undesired employee behaviors	Undesired employee behaviors
4 - Influence of structural aspects on employee behavior	- Formal mechanisms that reinforce OPEX behavior - Anecdotal evidence for unintended consequences of applying these
5 - Effective leadership behaviors	Effective leadership behaviors
6 - Leader standard work in your organization	- Scope of Leader Standard Work - Barriers & successful practices for implementation
7 - Miscellaneous	- Key Learnings - Next Steps

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Figure 16: Structure of interview guide for identifying supportive management behaviors

Based on the collected empirics from both the expert interviews and research group work, three cases are described in detail to illustrate how SFB is managed in practice in the context of pharmaceutical OPEX programs (cf. chapter 5.2.4). The cases were selected, since they depict the only OPEX programs within the scope of this research that formalize supportive management behaviors for impacting SFB to supplement MC.

4.3 Quantitative Analysis

To quantitatively study the effect of MC on the relation between operations-oriented OPEX practices and operational performance, a linear hierarchical regression analysis is applied using the six MC dimensions as moderators in the regression models (cf. Figure 17). In addition, principal component analysis (PCA), confirmatory factor analysis (CFA), and correlation analysis are used to evaluate the developed measurements for the independent variable (operations-oriented OPEX practices), the moderating variables (MC dimensions), and the dependent variable (operational performance).

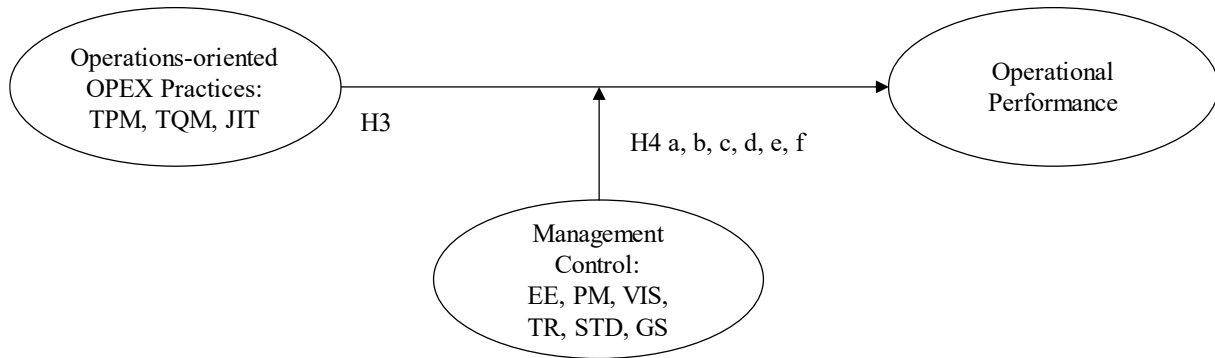


Figure 17: Measurement model for quantitative analysis

4.3.1 Data Collection

The quantitative analysis builds on data from real pharmaceutical manufacturing plants that was collected since 2004 through the St.Gallen OPEX Benchmarking (OPEX BM). The OPEX BM is a global benchmarking program at the ITEM-HSG that was administered to continuously measure the state of OPEX globally in pharmaceutical manufacturing (Friedli et al., 2013). At the time of performing the quantitative analysis, the OPEX BM database contained data from 381 plants. The questionnaire that was used to collect the data is structured along the St.Gallen OPEX model and covers all model elements depicted in *Figure 18*.

The OPEX BM assesses OPEX implementation along core OPEX program components from literature, based on OPEX practices that are adjusted for pharmaceutical manufacturing. Following (Cua et al., 2001), the implementation of the OPEX operating system is assessed based on operations-oriented OPEX practices that cover the categories TPM, TQM and JIT. Analogously, the implementation of the social OPEX subsystem, measured based on people-oriented OPEX practices in the category effective management system (EMS). These include, among others, management commitment and cross-functional qualification. Finally, the OPEX BM assesses the implementation of a third category of OPEX practices, which is considered to support both the OPEX operating system and the social OPEX subsystem. It is referred to in the St.Gallen OPEX model as basic elements and comprises the categories standardization and visual management (Friedli et al., 2013).

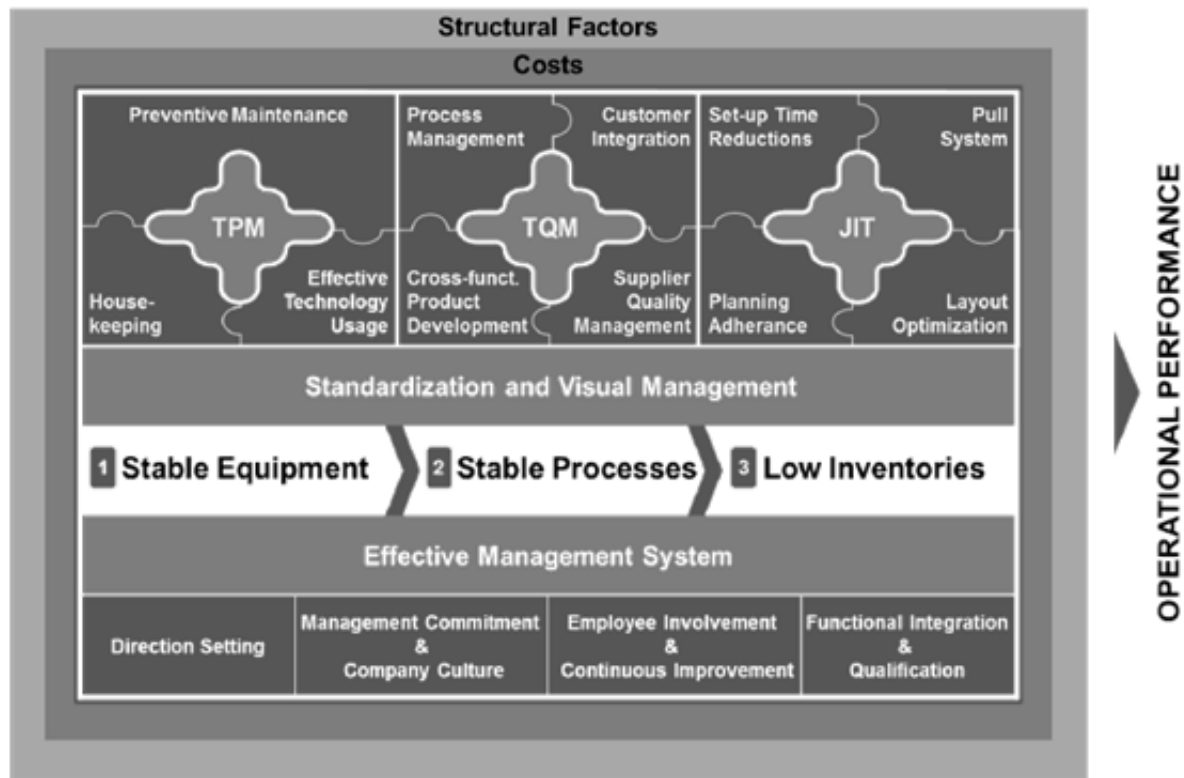


Figure 18: The St. Gallen Operational Excellence Model (Friedli et al., 2013)

Following the St. Gallen OPEX BM model, the questionnaire that is used for data collection consists of three main sections, as outlined in (Friedli et al., 2013, pp. 488–512). In the first section, information on corporate structure, plant type as well as cost and headcount structure are collected. The second section collects data on OPEX implementation, in terms of the implementation of both operations-oriented and people-oriented OPEX practices. Finally, metrics on operational performance are collected in a third section, to allow establishing a link between OPEX implementation and operational outcome.

To ensure quality of input data, the OPEX BM asks companies to circulate the questionnaire for data collection to qualified informants for each subsection. The first and the last section were typically filled out by middle or top managers to provide adequate contextual, cost and performance data, including plant managers, local or global OPEX program managers or managers from controlling. To facilitate an objective self-assessment of the OPEX practice implementation levels, the companies were further asked to involve relevant company representatives from different cross-functions, such as quality or maintenance, to fill out the respective section in teams.

4.3.2 Data Sample

The data sample for quantitative analysis comprises data completed by 2019 and contains 351 manufacturing plants from 37 countries.

Since several OPEX researchers have emphasized that the size of plants can affect the level of OPEX maturity implementation (Shah & Ward, 2003; Tortorella et al., 2018), plant size is used as a control variable in the quantitative analyses. A common site size classification in operations research is used to control for plant size, which distinguishes between small and medium sized companies on the one hand (<500 employees), and large plants on the other hand (>500 employees).

To further account for plant type, the three types brand manufacturers, generics manufacturers and contract manufacturers were used as additional control variables in the hierarchical regression models. The inclusion of plant type as control variable allows generalizing the research findings across different types of production that are commonly used to classify the operating models of pharmaceutical manufacturing firms.

Table 13 provides an overview of the sample composition based on the selected control variables. Brand, generics and contract manufacturers are represented to a similar degree in the data sample. Further, the majority of plants counts between 100-500 employees, with most plants being located in Europe.

Table 13: Sample composition of responses ($N = 351$)

<i>Region</i>	Europe	274	78%	<i>Plant type</i>	Brand manufacturer	152	43%
	North America	39	11%		Generics manufacturer	92	26%
	South/Mid America	10	3%		Contract manufacturer	107	31%
	Asia	7	2%	<i>Plant size</i>	Small (<100 Employees)	69	20%
	Africa	21	6%		Medium (100-500 Employees)	216	64%
					Large (>500 Employees)	54	16%

4.3.3 Measurement Instruments

To quantitatively study the variables of the measurement model (cf. *Figure 17*), measurements for each variable are developed based on the collected OPEX BM data. The developed measurements for the operations-oriented OPEX practices and the six MC dimensions are based on the collected data in the second section of the questionnaire (OPEX practice implementation). The underlying measurement items provide values on a Likert scale from 1 and 5. The performance score, in contrast, is based on normalized real continuous performance data that provides values on a continuous scale from 0 to 1 (*Appendix G*). *Table 14* provides an overview of the developed measurements for dependent, independent and moderating variables. In the following, the measurement development for all three variables is outlined.

Table 14: Overview of relevant measurement components

Variable	Category	Measurement/Indicator
Operations-oriented OPEX practices	JIT	Set-up time reduction
		Pull system production
		Layout optimization
		Planning adherence
	TQM	Process management
		Cross-functional product development
		Supplier quality management
		Customer integration
	TPM	Preventive maintenance
		Effective Technology Usage
		Housekeeping
Management Control dimensions	Planning	Goal Setting
	Cultural Controls	Employee Empowerment
	Administrative Controls	Training
		Standardized Work
	Cybernetical Controls	Visualization
Operational performance		Performance Measurement
	Quality - Internal	Rejected batches
	Quality - External	Customer complaint rate
	Dependability - Equipment	Unplanned maintenance
	Dependability – Internal	Production schedule adherence
	Dependability – External	On-time delivery
	Speed - Process Time	Deviation closure time
	Cost – Inbound Inventory	Raw material turns
	Cost – Outbound Inventory	Finished good turns

Operations-oriented OPEX practices

Since this dissertation seeks to quantitatively study the effects of the six MC dimensions on the effectiveness of the entire OPEX operating system, aggregating the implementation levels of the underlying operations-oriented OPEX practices into a single score is sufficient. Following (Cua et al., 2001) and using OPEX BM data, this score is calculated by aggregating the implementation levels of the operations-oriented OPEX practices from the categories TPM, TQM, and JIT. The aggregated score therefore represents the overall implementation level of OPEX practices from the technical subsystem of the St.Gallen OPEX model, which are based on the established measurement scales of (Cua et al., 2001).

To ensure an adequate measurement scale for the operations-oriented OPEX practices in terms of validity and reliability, a principal component analysis (PCA) is applied. Given both the recognized high interrelatedness between OPEX practices in literature (Shah & Ward, 2007), and the focus of this research on the interrelation between MC and the OPEX operating system as a whole, a one-factor model is adequate and therefore extracted using PCA (cf. chapter 5.3.1).

Management Control dimensions

To develop constructs for the six relevant MC dimensions, this research draws on survey items from the OPEX BM that represent people-oriented OPEX practices. The survey items include people-oriented OPEX practices from the categories EMS and basic elements of the St.Gallen OPEX model (cf. *Figure 18*). Multiple survey items are thereby combined into a measurement instrument for each of the six relevant MC dimensions.

To identify suitable survey items for each dimension, a two-step approach is followed. First, a content-based preselection of the survey items from the OPEX BM questionnaire is performed. Relevant survey items that are related to the six MC dimensions are then combined into the six constructs *visualization* (VIS), *standardized work* (STD), *performance measurement* (PM), *employee empowerment* (EE), *goal setting* (GS) and *training* (TR) (*Appendix H*). For example, survey items related to the use of visual boards to display performance objectives, current performance status or workplace information on the shop floor were combined in the construct *visualization*. Similarly, items related to the communication of objectives, or the linkage of individual objectives to organizational objectives were combined in the construct *goal setting*. In a second step, the preselected items are confirmed using confirmatory factor analysis (CFA) (cf. chapter 5.3.1).

Operational performance

The levels of balanced operational performance of pharmaceutical plants are assessed using metrics from the dimensions quality, dependability, speed and cost performance. These represent established dimensions of operational performance in OPEX literature (Bortolotti, Danese et al., 2015). While there is a common understanding in literature about these four dimensions, their suggested definitions and operationalization varies.

Eight real metrics are used to objectively measure the actual performance of pharmaceutical plants in the four performance dimensions (*Appendix I*). The metrics are identified based on the key objectives of TPM, TQM, and JIT that are depicted in the St.Gallen OPEX model (cf. *Figure 18*), since they are viewed as jointly facilitating balanced operational performance (Cua et al., 2001).

First, different types of dependability are distinguished. As TPM aims at maximizing equipment stability to avoid breakdowns, *unplanned maintenance* is included in the balanced performance score to account for equipment dependability. Other relevant metrics that are related to dependability are *production schedule adherence* and *on-time delivery*, which represent measures of internal and external delivery dependability.

Second, quality performance is distinguished into internal and an external quality, following (Shah et al., 2017). Internal quality is measured using the metrics *rejected batches*, whereas external quality is measured using the metrics *customer complaint rate*. These metrics correspond to the overall objectives of TQM, which is to stabilize processes in order to minimize defects.

Third, speed performance is measured in terms of *deviation closure time*, which can be viewed as a key determinant of a pharmaceutical plant's ability to release products in time.

Finally, the metrics *raw material turns* and *finished good turns* are used as indicators for inventory levels, based on the proposed objective of JIT to lower inventories. Since lower inventory levels are associated with lower operational cost, these two metrics can be viewed as measurements of cost efficiency.

Since the developed score calculates balanced operational performance based on real metrics of pharmaceutical plants that represent first order constructs, it does not aspire to represent a unidirectional theoretical construct. This is aligned with the theoretical sand cone model that is proposed by (Ferdows & Meyer, 1990). According to this model, potentially cumulative effects, in terms of high levels of achievable operational performance in all four dimensions, are considered to be dependent on the sequence of capability building (*Figure 19*). The four performance dimensions can therefore be cumulative under certain conditions, but they do not have to cumulate. Similarly,

scholars suggest that cumulative effects can depend on the emphasis placed on the improvement of different capabilities (Grössler & Grübner, 2006). Following the sand cone model, unidimensionality of the operational performance score is therefore not presumed.

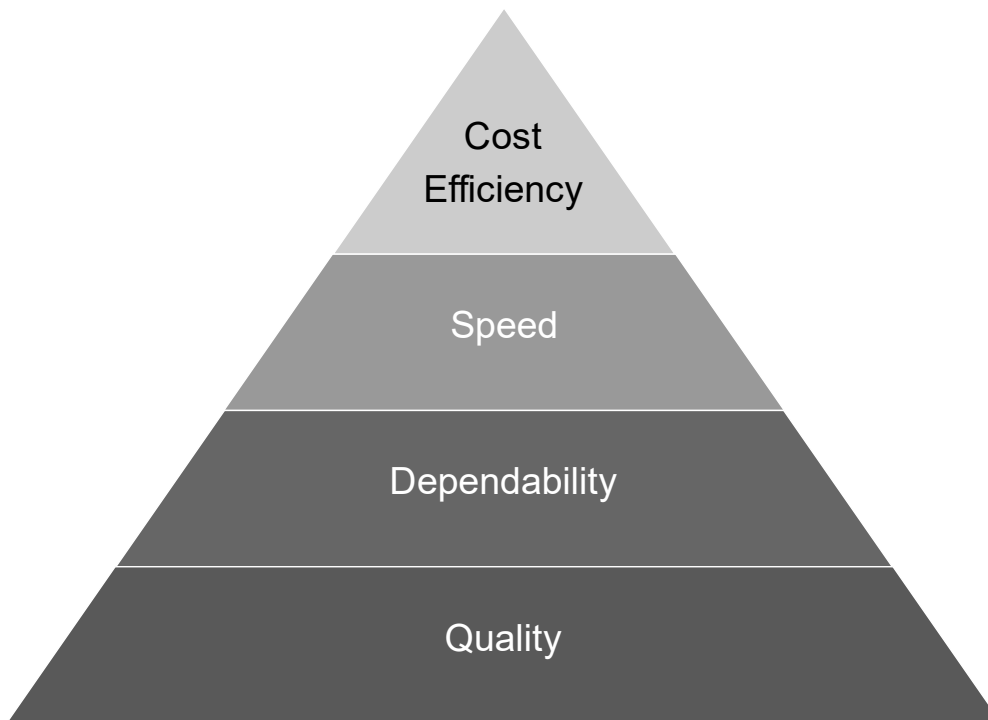


Figure 19: Sand cone model, adapted from (Ferdows & Meyer, 1990)

5 Empirical Findings

In the following, the findings from the mixed-method research are presented. From qualitative research, this study finds that the scope of relevant MC dimensions in pharmaceutical OPEX programs corresponds to the six MC dimensions that are derived from OPEX literature (cf. chapter 5.2.1). Further, barriers for impacting SFB with OPEX programs in pharmaceutical manufacturing are identified (cf. chapter 5.1) together with MBs that can help effectively impact SFB in this context (cf. chapter 5.2). The subsequent quantitative analysis suggests that MC acts as a moderator on the relation between the OPEX operating system and performance (cf. chapter 5.3). Finally, by drawing on both these findings and OPEX literature, a framework for impacting SFB in the context of pharmaceutical OPEX programs is derived (cf. chapter 5.4). This chapter closes by discussing the practical and theoretical implications of the research findings (cf. chapter 5.5).

5.1 Contextual Barriers

The expert interviews suggest that contextual barriers exist in the pharmaceutical manufacturing environment that limit the manufacturer's ability to impact SFB with pharmaceutical OPEX programs in desired ways. Overall, eight barriers are derived that will be outlined in the following.

1 – Procedural regulation

Pharmaceutical manufacturers need to comply with regulation that aim to assure quality of drug products by the diminishing risks that are inherent in any pharmaceutical production. These include risk of cross-contamination, mix-ups or false labelling (WHO, 2014). Pharmaceutical regulation is therefore intended to protect the consumer from purchasing products that are unsafe or ineffective. This is driven by the fact that consumers typically cannot easily assess the quality of pharmaceutical products on the market themselves. Depending on the target market for a respective drug, pharmaceutical manufacturers need to adhere to standards defined by different national health agencies, which can result in significant regulatory complexity. For example, for vaccines production the World Health Organization (WHO) lists a total of 23 national health agencies that are defined as functional, based on a set of criteria from a global benchmarking. These include, among others, the FDA, the European Medicines Agency

(EMA), or the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) (WHO, 2019).

The basis for assessing regulatory compliance is depicted by so called Good Manufacturing Practices (GMP), which define minimum requirements that manufacturer must meet in their production processes (EMA, 2008). These practices are also referred to as current Good Manufacturing Practice (cGMP), indicating that GMP can change over time and that manufacturers always need to ensure that they follow state-of-the-art practices.

For drugs that are, for instance, intended for the U.S. market, GMP compliance is enforced by the FDA under the Code of Federal Regulations in Title 21 (FDA, 2020). To help manufacturers comply with GMP requirements, the FDA publishes guidance documents that represent the FDA's current thinking on a GMP relevant subject. Additionally, it conducts public outreach to outline GMP requirements together with current policy documents. Notable examples of guidance documents include International Council for Harmonization (ICH) Quality documents, such as the Q10 document on pharmaceutical quality systems (ICH, 2008). It outlines requirements for an effective pharmaceutical quality system for developing and manufacturing pharmaceutical drug substances and drug products. It is also recognized by other international government agencies, such as the EMA.

To assure compliance with GMP requirements, pharmaceutical manufacturing operations are guided to a large extent by SOPs. Manufacturers need to ensure that all operations involved in pharmaceutical production are “clearly defined, validated, reviewed, and documented, and that the personnel, premises and materials are suitable for the production of pharmaceuticals and biologicals including vaccines” (WHO, 2021). According to the WHO, this covers all operations from receipt of materials, processing, packaging, repackaging, labelling, relabeling, to completion of the finished product, including aspects of “testing, and responses to product defects and complaints”. To assure they meet these requirements, manufacturers define SOPs for all areas of operations that are mentioned above. Among the most critical SOPs are those that guide shop floor activities, since they directly affect product quality. For the same reason, shop floor personnel is instructed to follow SOPs closely, which has a significant influence on the way that they conduct themselves.

Non-compliance with regulatory requirements can have severe consequences for pharmaceutical manufacturers. As GMP regulation aims to ensure that products are produced and controlled, as required by the marketing authorization, violation of GMP requirements can result in fines, recall, loss of regulatory approval, seizure, or even jail

time (FDA, 2021). In case of violation of U.S. GMP regulation, the FDA will inform the manufacturer about its assessment in an official letter called warning letter. The FDA describes the warning letter procedure as follows:

“When FDA finds that a manufacturer has significantly violated FDA regulations, FDA notifies the manufacturer. This notification is often in the form of a Warning Letter. The Warning Letter identifies the violation, such as poor manufacturing practices, problems with claims for what a product can do, or incorrect directions for use. The letter also makes clear that the company must correct the problem and provides directions and a timeframe for the company to inform FDA of its plans for correction. FDA then checks to ensure that the company’s corrections are adequate.” (FDA, 2019a).

As some interviewees point out, violation of GMP regulation is among the biggest operational risk for a pharmaceutical manufacturer. On the example of the U.S. market, in case the FDA finds the response of a company to a warning letter not satisfactory, the company may be prohibited to produce any more product at the inspected site for the U.S. market. The FDA may further forbid the company to produce any more product for the U.S. market, if it has general concerns about the quality system that is in place (FDA, 2021). Accordingly, GMP compliance is viewed as a business priority for pharmaceutical manufacturers and is therefore taken extremely serious in everything that the manufacturer does in their operations.

The example of PharmaCo C illustrates how procedural regulation can translate into pharmaceutical manufacturing practices that can in turn impact SFB. The company recently made the decision to transition from a demand-and-control oriented approach to managing work teams to more autonomous teams. The management decision was heavily motivated by ever increasing regulatory requirements. In this context, the company finds itself optimizing against a moving target in the GMP environment. To cope with these changing requirements, the company believes that work teams need to be put in a position where they can respond to changes affecting their working environment more effectively and in a timelier manner.

To achieve this goal, the company aims to enable work teams to assume more responsibility for continuous improvement of the processes that they work on. This, however, does not equate to work teams being fully detached from regulatory or management oversight. Instead, the company’s concept of autonomous teams rather describes a shift from people-focused guidance to system-focused guidance. In both cases, the room for maneuver of the work teams is constrained.

In the case of people-focused guidance, work teams are asked to accurately follow predefined work instructions. Improvements in practices or procedures are largely developed centrally and then rolled out to the teams. In this system, work teams have limited room for adjustments of production processes, as management intends to control SFB based on detailed guidelines and SOPs. In contrast, the system-focused approach, aims to guide SFB by defining a sufficiently narrow framework, within which work teams can make decisions and can adjust the systems of production in alignment with existing SOPs. The concept of autonomous teams at PharmaCo C therefore corresponds to a shift in the type of guidance, rather than to a shift towards full autonomy.

Despite significant improvements from introducing autonomous teams on the shop floor in the past years, the company reports profound challenges for implementation in pharmaceutical manufacturing. While the locus for continuous improvement was, to a large extent, successfully moved closer to the production lines, the company recognizes challenges for sustained shop floor engagement for two reasons. First, work teams are often not in a position where they can own a process or sub process in order to make timely decisions. This would require, on the one hand, that the size of the team that assumes responsibility is adequate to ensure the team members can assume the necessary roles and responsibilities. PharmaCo C has identified 15 to 20 people as the upper limit for team size. To ensure adequate team sizes, processes need to be redesigned, since the typical team size is currently larger. However, as the company is experiencing that a such required reorganization can be time consuming in the pharmaceutical environment, where personal is usually highly specialized. This can hinder the adoption of autonomous teams as an alternative management approach to command-and-control. Second, the framework that directs SFB tends to narrow over time, as new procedural regulations need to be accounted for. According to the company, a challenge that arises from this is that work teams can become less or even disengaged in OPEX, in case a perceived narrowing of their room for maneuver is not comprehensibly set in context by management.

The case of PharmaCo A provides another example for how procedural regulation can be a challenge for impacting OPEX behavior. When the company's OPEX program was still relatively new in 2017, many sites were skeptical whether it can be implemented. Concerns included that using trending performance indicator on a printout or on a performance board may not represent validated information and can therefore lead to compliance issues with regulators. In the meantime, this concern was somewhat diminished, as many teams adopted the view that they can control their own performance without any validated boards or sheets. This example shows, however by

the first reaction of many production teams that the intended effects of MC in OPEX programs can overlap with behavioral implications of GMP requirements, which shop floor teams simply must adhere to. They can further conflict with each other, for example, in case the worker's understanding of regulatory requirements does not align with the behavior that is expected as part of the OPEX program.

The culture that has developed in some areas of the organization over the course of the past decades can be characterized by worst-case thinking, as the interviewees describe it. That is, shop floor employees are incentivized to always protect themselves against any wrong-doing multiple times. As a result, the focus is sometimes rather on documentation than on the actual content of their activities. As the interviewees describe, having a documented rationale for everything that is done on the shop floor to ensure compliance has thus become the main concern in some areas. From a cultural point of view, such a focus can severely limit the ability of shop floor personnel to engage in OPEX.

In many areas, the company has now gone through a learning curve. Shop floor personnel and managers alike have noticed that there is much more freedom than previously expected. That by itself is viewed as progress in terms of the company's ability to affect the right SFB for OPEX.

In summary, the examples outlined above show how procedural regulation in pharmaceutical manufacturing can impact SFB as well as the manager's abilities to impact SFB for OPEX. Counterproductive effects of procedural regulation can include lack of engagement of shop floor personnel and slow decision-making. The outlined examples further show that counterproductive effects can arise from various sources, such as difficulty to organize shop floor personnel in autonomous teams along adequate processes, concerns about integration with GMP regulation, or lack of transparency on OPEX criteria that define organizational guard rails for impacting behavior.

Table 15: Behavioral implications from procedural regulation

Barrier	Description	Behavioral implication
Procedural regulation	Regulation governs various aspects along the manufacturing process, including sequence of process steps, work instructions, process parameters, access rights to manufacturing and quality related information, equipment and machine specifications, or protocols for dealing with deviation.	• Change aversion • Perceived conflicts • Shallow empowerment • Lack of OPEX engagement • Lack of experimentation • Complacency

2 – High effort to execute changes

Many of the studied manufacturers still run into limitations for continuous improvement that are attributed to the pharmaceutical manufacturing environment. For instance, much of the OPEX program of PharmaCo A is conceptually based on experimental approaches. Thus, rather than planning large improvement projects and trying to foresee all implications of making respective changes, the intended OPEX approach is to first conduct a solid analysis of the problem, and then to switch quickly to making small changes to the process and experimenting with the effects. While conceptually, there is a general acceptance of this procedure in the organization, in practice, this is only applied to a limited extend.

The company highlights the issue of validation as one big hurdle, since most post-approval changes typically require regulatory filings of some sort. For example, the company was recently working on a packaging system and has identified a problem at one of the swiss sites that management wanted to solve based on elements of the OPEX program. They derived necessary actions and found that they would need to intervene in the validated area of the system. This is when the pen was literally dropped, and all improvement efforts were halted. This has generally been the experience at this one site and typically alternative approaches are then explored. In the worst-case, this can lead to not addressing the problem, as in the case of the packaging system. While there are possible solutions to addressing this phenomenon, they are currently not practiced at the site.

One way in which this issue could be overcome according to the interviewees could be using appropriate tools and methods that help avoid unnecessary intervention in the validated environment. One way that can help address the issue is, for instance, using simulation and then only making the changes and revalidating, once one can be sure that the intended solution will work. Another way to remove roadblocks for impacting SFB that does not require as much effort as simulation could be so-called cardboard engineering, where solutions are tried out with simple means outside of the validated environment. As the company points out, this could also happen during regular maintenance appointments, so that the operations are not affected by the experiment.

Table 16: Behavioral implications from high effort to execute changes

Barrier	Description	Behavioral implication
High effort to execute changes	Post-approval changes of pharmaceutical manufacturing processes involve high effort for risk management, documentation and re-validation of new processes and procedures.	• Complacency • Prioritization of incremental improvements over radical improvement • Lack of experimental improvement • Change aversion

3 – Change aversion

The mindset on the shop floor of pharmaceutical manufacturing firms tends to be change averse, which can depict a barrier for adopting the intended behaviors for OPEX. Common concerns of shop floor employees at the studied companies include, for example, that the additional transparency that is created by OPEX programs can potentially cause compliance related inconveniences. Common concerns of workers and managers alike include for example, the question: “What will happen if an auditor walks through the plant today and sees how bad the achieved yield is at the moment?”.

The qualitative findings suggest two potential success factors for avoiding change averse mindsets on the shop floor. The first success factor is maintaining a good working relation with regulators at the site, so that a dialogue on related peculiarities can take place. According to the interviewees, increased levels of transparency on the shop floor can also be perceived positively by an auditor, since it can be viewed as an indicator for how well production teams are dealing with their processes in well-founded ways. A second success factors for avoiding change averse mindsets is proper goal setting as part of strategy deployment to facilitate some top-down control over to ensure continuous improvement is properly prioritized on the shop floor. To illustrate, to enable shop floor workers to adequately balance their daily efforts between process execution and improvement, one must first know where the biggest potentials lie for a plant or a production team, where bottlenecks are located, where it is worth making certain improvements, and so forth. This is where there are still gaps in the studied companies, since often such knowledge on the operational priorities for each plant, area and team do not yet exist on a comprehensive level.

In the cases where it is clear to the head of department or head of division that certain deficits exist that need to be solved, it is typically not a problem to address and solve the issues. Hence, when goals are clear and well-focused, the findings suggest that shop floor employees are more likely to adopt behaviors that support OPEX. Accordingly,

proper goal setting, for example as part of an end-to-end value stream analysis, is viewed as a key factor for ensuring that there is a recognized need for OPEX amongst workers, which then opens doors for shop floor personnel to adopt adequate behaviors.

Finally, creating transparency about what needs to be improved can not only facilitate the right behaviors, it can also help empower shop floor workers to draw support from cross-functions that may be critical for resolving the problem. This is especially critical, since clarifying what can be changed in the GMP environment often requires cross-functional exchange and support.

Table 17: Behavioral implications from change aversion

Barrier	Description	Behavioral implication
Change aversion	Changes of existing processes or procedures to achieve operational improvements are perceived as potential risks to quality, patient safety and regulatory compliance. As a result, OPEX and quality are viewed as conflicting dimensions, which nurtures change aversion and requires constant management attention.	• Lack of clarity regarding common purpose and shared vision • Confusion of shop floor personnel • Deprioritization of CI • Lack of best practice sharing • Lack of leadership support • Lack of recognition for improvements • Lack of pursuit of cost efficiency

4 – Separation of Quality from OPEX

All studied companies have clearly separated the quality organization from the OPEX organization in connection with regulatory requirements. Against this backdrop, some companies have observed a parallelism between some components of OPEX programs and components of pharmaceutical quality systems, which can act as a barrier for OPEX SFB in pharmaceutical manufacturing. In cases of doubt regarding issues of high importance for the business, there is a tendency to fall back on the quality system to the neglect OPEX program components. The OPEX program is therefore often viewed as a useful supplement to the quality system. Yet, as one interviewee pointed out: “When the house is on fire, the OPEX program is no longer so important”.

Regarding the degree to which GMP requirements limit OPEX in pharmaceutical manufacturing, the findings suggest that there is sometimes the challenge that a plant attempts to utilize OPEX program elements to make improvements, while it still has a complete quality system in the background. One example is problem solving. To identify and solve the root cause of a problem the companies can on the one hand draw on relevant OPEX program elements, such as problem solving. On the other hand, they have a quality system that includes methodologies for corrective and preventive actions

(CAPAs), as required by the FDA. It describes in detail how to perform root cause analysis, or quality investigations. The parallelism between the OPEX program element problem solving and CAPAs there depicts one example for an overlap between OPEX programs and the quality system. As the interviewees emphasize, both are based on root cause analysis and describe how to identify problems, how to correct them and how to prevent them from reoccurring. They further indicate that if along the production process a company notices deviations, it is required by regulators to accurately evaluate the problem, and if applicable, to derive actions to fix it and to prevent it from happening again.

Another parallelism between OPEX programs and the quality system that is linked to CAPA is the topic of CAPA effectiveness. It describes how CAPA needs to be performed to make a CAPA effective. It represents another example of an issue that is of relevance in both the quality system and the OPEX program. However, they are often these not harmonized, which can lead to unintended behaviors and ambiguous target setting.

Overlaps like the ones outlined above can not only lead to confusion among shop floor workers, but they can also have training implications. Due to regulatory requirements, all shop floor workers need to complete root cause and CAPA trainings. As one interviewee points out, regulatory compliance requires that all workers are trained according to their role profile. The performed trainings then need to be fully documented in the training system.

The findings suggest that from the perspective of shop floor personnel, the process of going through hours of classroom training connected to the quality system, only to then have OPEX managers expect them to follow a different methodology as part of the OPEX program can be confusing. This separation can hinder the adoption of the intended OPEX behaviors.

One way to deal with the parallelism between the two systems in a way that can avoid unintended consequences is to integrate and harmonize the two systems. On the one hand, there is an overlap between the CAPA methodology and the OPEX problem solving methodology, as outlined above. On the other hand, the former only uses a subset of the latter. The quality system would therefore potentially benefit from OPEX problem solving techniques. According to one interviewee, an integration could help reduce the number of recurring deviations, which depicts a typical indicator for quality performance in pharmaceutical manufacturing firms. Specifically, OPEX programs can facilitate finding root causes of identified problems, which can contribute to a reduction of the number of reoccurring deviations.

The findings suggest that the studied companies generally have adequate mechanisms for facilitating post approval changes. For example, they commonly have procedures for evaluating the extent to which changes affect the product. In theory, operational improvements are therefore safely feasible in pharmaceutical manufacturing, without negatively affecting patient safety. Yet, the separation of quality and OPEX organizations can be viewed as a barrier that hinders shop floor workers from pursuing improvement opportunities, while ensuring compliance with GMP requirements.

Table 18: Behavioral implications from separation of quality from OPEX

Barrier	Description	Behavioral implication
Separation of quality from OPEX	Regulatory requirements demand oversight function of quality organization, which results in a strict separation of responsibilities for tasks related to quality assurance and quality control from responsibilities for production along functional boundaries.	• Silo thinking • Limited empowerment of shop floor • Lack of shop floor engagement in OPEX • Change aversion

5 – Perceived regulatory uncertainty

Perceived uncertainty about what operational changes can be made in the regulated pharmaceutical environment represents the fifth identified contextual barrier for OPEX behavior on the shop floor. This barrier primarily relates to the perception of practitioners, since pharmaceutical regulation is recognized as relatively slow moving, which theoretically allows practitioners to catch up with any changes in the regulation. Exceptions depict health crisis, which typically increase the speed of decision making by regulators, such as the FDA. The most recent example is the global COVID-19 pandemic, which has led to several short-term changes to pharmaceutical regulation. While the clarity of pharmaceutical regulation in general was not highlighted as an OPEX barrier by the interviewees, the complexity and the everchanging nature of regulatory requirements, resulting in perceived uncertainty, were highlighted as a relevant barrier.

Perceived uncertainty can affect OPEX behavior on the shop floor in different situations. On the example of post-approval changes, which refer to operational changes after a process has been initially validated, two situations have been identified. The first example refers to preconditions for post-approval changes. To illustrate, shop floor personnel may be uncertain whether changes to an identified issue are feasible in general from a regulatory standpoint, which can lead to acceptance of mediocre performance.

Examples include the use of tools, or certain practices. Another example refers to the required effort and timeline for post-approval changes, which may lead to the implicit or explicit definition of thresholds below which an improvement opportunity is not considered attractive enough to be pursued. This implicit or explicit prioritization of opportunities can result in a lack of incremental improvement opportunities for shop floor workers, which can in turn result in a lack of empowerment and a lack of engagement in CI.

Table 19: Behavioral implications from perceived regulatory uncertainty

Barrier	Description	Behavioral implication
Perceived regulatory uncertainty	Post-approval changes in the manufacturing processes can lead to perceived uncertainty regarding preconditions, effort, and timeline for successful implementation.	• Lack of experimentation • Acceptance of mediocre performance • Lack of opportunities for incremental improvement • Lack of empowerment of shop floor • Lack of engagement in CI

6 – Design of SOPs for regulatory use

All studied companies emphasize that the SOPs that they use in manufacturing are primarily designed for regulatory use. Those that have developed co called standard work concepts as part of their OPEX program have clearly separated it from SOPs. Hence, only these concepts of standard work are typically viewed as components of the studied OPEX program.

Standard work depicts the currently best-known way of performing a specific task, and it as designed by colleagues. It involves among others use of role cards, use of planning and scheduling tools and it has the concepts of process confirmation and CI loop associated with it. In contrast, it doesn't depict regulatory and quality control practices. Hence, it doesn't tell, for example, what dial to push, what number to enter, and so forth. That would all be documented in the SOP.

The following example from PharmaCo F illustrates the reasoning behind why many pharmaceutical companies decide to clearly separate the two systems. On the example of PharmaCo F, a SOP would define, for example, that a step A should be followed by a step B and that step A should take 10 minutes, whereas step B should take 30 minutes. If now the company deviates from these defines steps, for example, if these steps are done in parallel or in a different order, then this would represent a deviation from the

standard, which then would need to get recorded in terms of describing why the deviation occurred, what went wrong in detail and so forth.

“Standard work is never used to describe how something should be done. Standard work is non-GMP. It just states in what sequence things should be done to maximize the efficiency and consistency of how that process gets executed and the timing in terms of how long should process steps take.”

We find that all studied companies are very mindful of the potential parallelism between SOPs and standard work. Typically, in order to avoid regulatory complications, pharmaceutical companies make it very clear what standard work is, and what it is not in terms of being part of the GMP system. Surprisingly, none of the studied companies considers SOPs a part of OPEX related standard work concepts.

In the light of this parallelism, we find that having to make this distinction between SOP and standard work can act as a barrier for OPEX in pharmaceutical manufacturing. Separating these two systems requires companies to frequently run a fine line between avoiding internal or external regulatory resistance on the one hand and providing employees with best-known ways of doing things that can be easily updated and improved. To illustrate, on the one hand, pharmaceutical companies need to manage regulatory concerns in case of overlaps between standard work concepts and SOPs. On the other hand, making a standard work document a GMP document requires companies to then treat it as a controlled document as part of the GMP system, which binds resources for managing the GMP documents and limits abilities for CI.

The existing approaches to standard work in pharmaceutical manufacturing suggest that there is room for improvement irrespective of the respective content of SOPs. We find that SOPs tend to be written at a detail level that aims to avoid having to process an inordinate number of deviations. To illustrate, if a SOP is very stringent and a company does not follow some of the specified aspects of the SOP, that is automatically considered a deviation in pharmaceutical GMP systems. As a result, SOPs get written more generally, which can leave relevant descriptions open to interpretation. As a result, this can lead to variability in the process and in worst case to a defect.

In the light of these existing limitations, we found that there is initial thinking evolving on gearing SOPs more towards human performance. Traditionally, SOPs are numbered paragraphs of work instruction that are typically used to train employees and to document compliance with regulatory requirement. They are usually not optimized for guiding behavior in the process and can therefore be difficult to follow, which make them unhandy for daily use. To illustrate, SOPs typically entail multiple written pages,

and lack visualization or other techniques to ensure ease-of-use. Against this backdrop, we found that a couple of companies recently started thinking about making SOPs more visual by a combination of words and visuals. One example includes adding to each section a set of bullets with easy-to-understand and easy-to-remember description of process steps in the order in which they should be done. Another example includes adding visuals to SOPs that show, for instance, what the outcome should look like, what dial should be turned, or where the location of a certain dial is, in order to help a person that needs to execute a task to see the different things they need to do visually in addition to written description of process steps.

Table 20: Behavioral implications from design of SOPs for regulatory use

Barrier	Description	Behavioral implication
Design of SOPs for regulatory use	Two types of process standards have emerged in pharmaceutical manufacturing that need to be handled by operations personnel, resulting in increased task complexity and higher cognitive load. SOPs, on the one hand, are primarily designed for regulatory use, whereas the concept of standard work is designed to support daily tasks with a focus on OPEX.	• Lack of clarity of common purpose and intent of SOPs • Extra work/non-value adding work • Improvement not included in routine work of shop floor personnel • Lack of engagement in CI

7 – Knowledge intense value creation

Knowledge intense value creation is identified as a seventh contextual barrier. It is viewed as a relevant barrier in pharmaceutical manufacturing, due to the combination of its affiliation of to the process industry and its operations in a regulated environment.

The affiliation of pharmaceutical manufacturing to the process industry is viewed as a subcomponent of the identified barrier, based on high interconnectedness of operational issues. In contrast to discrete manufacturing, individual tasks along the value creation processes are more interconnected. To illustrate, based on the sequential nature of value creation in the process industry, downstream processes and upstream processes can often only be optimized comprehensively. While OPEX generally seeks to facilitate holistic operational improvement, this can be viewed as an additional obstacle in pharmaceutical manufacturing. On the one hand, even incremental improvements can require advanced process knowledge. On the other hand, tasks are often highly specialized, which can foster working in silos. In combination with often limited capacity of shop floor personnel to engage in OPEX, due imposed priorities by upstream

or downstream processes, this can significantly limit the comprehensiveness of process knowledge that shop floor personnel may obtain to meaningfully engage in OPEX.

In addition to the requirements from operating in a process industry, the regulatory environment requires additional knowledge. To illustrate, in addition to comprehending a wide range of regulated procedures only to perform the daily tasks, shop floor workers need to have a firm knowledge of relevant regulatory requirements that may affect the feasibility of operational changes. Examples include product life cycle constraints, which may predetermine the feasibility of operational improvements.

Table 21: Behavioral implications from knowledge intense value creation

Barrier	Description	Behavioral implication
Knowledge intense value creation	High degree of task specialization combined with largely scientific job profiles can lead to pronounced silo thinking and lack of OPEX capacity. This can be even amplified by fluctuation of key personal and high pressure to continuously produce.	• Work in silos • Lack of awareness for OPEX topics • Lack of OPEX engagement • Resistance to change • Confusion/Inertia

8 – Lack of sense of urgency

One of the barriers for impacting SFB with OPEX programs that has been mentioned in most interviews is lack of sense of urgency for improvement on the shop floor. In contrast to other industries where cost efficiency and competition is communicated as one of the main rationale for adopting OPEX, the general view in pharmaceutical manufacturing is that as a performance dimensions cost comes only after product quality respectively patient safety. This has led in many organizations to difficulties to communicate the sense of urgency for adopting OPEX practices and to an ambiguous communication of goals. One interviewee has described a situation where there is a lack of focus in terms of what should be improved in contrast to what can be improved.

The pharmaceutical environment is associated with historically high profit margins given patent protection against competitors for long periods of times. However, recently pharmaceutical companies have put stronger emphasis on cost efficiency among others given increasing product development cycles and increasing cost, increasing competition from generic drug manufacturers after patent expiration, cost pressured western healthcare systems.

Having clear focus on what to improve and clearly communicating the sense of urgency has been identified in the interviews as a success factor for impacting SFB

adequately. To illustrate, one German site of PharmaCo A, was recently trying to increase the yield of a bottling plant. By then, the site has lived with a relatively poor yield for a long time before different improvement activities were initiated supported by the global OPEX organization. The site management was involved as well as the finance department, and it could be shown what the actual losses were that were intended to be reduced. Based on the joint effort the decision was made that the site would focus on yield to improve its performance. First, the management attention was there, because the site management realized that they were losing a lot of money through this lack of performance. So, it has become too significant to ignore. Secondly, it also set a focus, whereas before the teams had a lot of different things at the plant that could as well be improved but did not get followed-up upon. Setting the focus on an important metric, such as on yield, allowed the site to orchestrate all improvement activities around improving yield as the main metric, which was perceived as a big advantage by both management and shop floor personnel. Therefore, one lesson is that having a clear focus helped impact the right behavior. Before that, even given the recent introduction of the OPEX program, the attitude was of the kind of “what can you improve?”. In turn, making the switch to “what do we really need to improve?” helped empower the shop floor employees to focus on the right things and getting proper cross-functional support.

By setting a clear focus, also one of the above outlined barriers of change aversion could be overcome in parts. In the case, the company has among others made technical modifications to the plant, which were on the one hand associated with a real investment and on the other hand intervened in a validated area. In this case it required an important goal in order to make necessary changes and remove change averse tendencies of both management and shop floor personnel.

Table 22: Behavioral implications from lack of sense of urgency

Barrier	Description	Behavioral implication
Lack of sense of urgency	Historically high profit margins and pharmaceutical business models that prioritize R&D, patent protection or other strategies to ensure exclusivity can limit the sense of urgency for operational improvement, which in turn can act as a barrier for commitment of organizational members to OPEX.	• Acceptance of mediocre performance • Complacency • Reluctance to give negative yet constructive feedbacks • Lack of recognition for implementing improvement from leaders • Perception of OPEX as voluntary or “nice to have” activity • Lack of role modelling • Wrong balance between projects and daily improvements

Conclusion

The qualitative findings suggest that the pharmaceutical manufacturing environment can impose barriers that can impact shop floor behavior of pharmaceutical manufacturing firms. Since the management of shop floor behavior has been identified as an OPEX success factor, these findings provide empirical support for the need to adjust the management approaches for OPEX to circumstance, as suggested by scholars such as (Franco-Santos & Otley, 2018).

All identified contextual barriers can be linked to the categories of OPEX barriers proposed by (Zhang et al., 2017) (cf. Table 9). Using the proposed categories, the identified barriers can be assigned to one of the four categories *knowledge*, *conflicts*, *employee & culture* and *resources*.

Table 23: Barriers for OPEX behavior in pharmaceutical manufacturing

No.	Barriers	Knowledge ^a	Conflicts ^a	Resource ^a	Employee & Culture ^a	Financial outcome ^a
1	Procedural regulation		•			
2	Change aversion				•	
3	Separation of quality from OPEX				•	
4	Perceived regulatory uncertainty	•				
5	Design of SOPs for regulatory use		•			
6	Knowledge intense value creation	•				
7	Lack of sense of urgency				•	
8	High effort to execute changes			•		

^a Categories of OPEX barriers proposed by (Zhang et al., 2017)

In conclusion, the following hypotheses can therefore be confirmed based on the qualitative findings.

H1a: *Knowledge-related barriers for OPEX behavior exist that are pharma specific.*

H1b: *Conflict-related barriers for OPEX behavior exist that are pharma specific.*

H1c: *Resource-related barriers for OPEX behavior exist that are pharma specific.*

H1d: *Employee & Culture-related barriers for OPEX behavior exist that are pharma specific.*

The last hypothesis cannot be confirmed based on the findings, since no pharma-specific barriers were identified in the category *financial outcome*.

H1e: *Financial outcome-related barriers for OPEX behavior exist that are pharma specific.*

The findings suggest that the pharmaceutical environment can impose additional barriers for impacting OPEX behavior that may not be a concern in other industries. At the same time, no new barriers were identified that cannot be assigned to either of the five barrier categories in literature. In general, pharmaceutical manufacturers must therefore deal with the same overarching barrier categories as companies from other industries. Practitioners seeking to impact SFB to support OPEX in pharmaceutical manufacturing should therefore be mindful of the additional pharma-specific barriers, while being open to successful practices from other industries that address the shared overarching barrier categories. Finally, practitioners should also be mindful of potential effects that may arise from combinations of multiple of the identified barriers. For example, the combination *perceived regulatory uncertainty* and *high effort to execute changes* can result in a lack of experimentation, which can result in a lock-in on the status quo. This pharma-specific phenomenon is described by one interviewer as a compliance trap.

5.2 Supportive Management Behaviors

In the following, the interrelation between MB and MC are studied, which plays a central role for supporting OPEX in the research model. In the first subchapter, an overview of people-oriented elements of the studied OPEX programs that are derived from initial desk research is presented (cf. chapter 5.2.1). Following (Macintosh & Scapens, 1990) conceptualization of structuration, unintended consequences of MC are then identified as a basis for establishing a link between MC and MB (cf. chapter 5.2.2). In the third subchapter, the intended MBs collected from research group work and expert interviews are presented as a basis for identifying supportive MBs for impacting SFB. Next, those MBs that bear the potential to mitigate unintended consequences of MC are outlined (chapter 5.2.3). Finally, based on the derived set of MBs, the ways in which the studied OPEX programs integrate MC with MBs to influence SFB are studied. For this purpose, the management standard work (MSW) concepts of three selected OPEX programs are reviewed in terms of formalized MBs, as well as linkage between these MSW concepts and MC (chapter 5.2.4).

5.2.1 People-oriented OPEX Program Elements

The analysis of ten modern pharmaceutical OPEX programs shows that pharmaceutical companies adopt many of the core OPEX program components that are emphasized in the OPEX literature. Like companies from other industries, they follow a holistic OPEX program approach, comprising a technical and the social OPEX system. Common components of the technical OPEX subsystem include pull production, and effective technology usage, whereas components of the social OPEX system include, for example, employee involvement or standardized work (cf. chapter 3.3). Since we are interested in impacting SFB, we focus in the following on the people-oriented elements of the studied OPEX programs.

Despite the similarities between the OPEX program components in literature and in the real pharmaceutical companies, we find that pharmaceutical companies also include people-oriented components that are more granular or not represented at all by the common components in OPEX literature. Components that are not adequately represented by common OPEX program components include, for example, tiered accountability, structured meetings, process confirmation, management review, performance dialogue or management standard work.

The concept of tiered accountability aims at involving all organizational members in the process of continuous improvement by cascading down accountability across all hierarchical levels of the organization. Similarly, structured and cascaded meetings aim

at aligning all organizational efforts toward a common goal, by involving everyone on a regular basis in meetings on the current status of operations to coordinate improvement activities. Management review is a concept specifically aimed at facilitating effective decision making by management based on regular review of current status of operations, for example, regarding performance, or risks. Closely linked to management review is the concept of performance dialogue, in which supervisors get in dialogue with their employees to reflect on current performance levels. It can be viewed as a mechanism for identifying necessary improvements, for aligning on suitable actions and for engaging employees in the process of CI. Finally, some pharmaceutical companies explicitly include management standard work as part of their OPEX program, which covers the embedding of routing management tasks in the OPEX program. Table 24 provides an overview of people-oriented components that are addressed by the studied pharmaceutical OPEX programs, including whether they are explicitly or implicitly addressed. Elements are considered implicit elements, if they are indirectly considered as part of the OPEX program without including the respective mechanism explicitly. For example, a program may implicitly address management behavior, by including program elements such as leadership style or top management support. Similarly, an OPEX program may implicitly include the element goal setting by including elements related to organizational direction setting such as corporate vision, or strategic priorities.

Table 24: People-oriented elements of pharmaceutical OPEX programs

OPEX program elements	PharmaCo A	PharmaCo B	PharmaCo C	PharmaCo D	PharmaCo E	PharmaCo F	PharmaCo G	PharmaCo H	PharmaCo I	PharmaCo J
Continuous improvement (CI)	•	•	•	•		•	•	o	•	•
Problem solving	•	•	o	•	•	o	•	•	•	
Employee involvement/empowerment ^a	o		o			•	•	o	•	•
Cross-functional teams ^a			•				•			•
Recognition	o			•				•		
Purposeful communication				•				•	•	
Training ^a	•	•	•	•	•	o	•	•	•	
Job rotation				•						
Knowledge management/sharing		•		•	o	o		•		
Strategy deployment/Goal setting ^a	•			o		•		•	o	o
Gemba	o		•	•	o	o	•	o	•	
Values & beliefs ^a	o		o			o	•	o		•
Structured meetings/meeting cascade/escalation	•	•	•	•	o	•		•	o	
Tiered accountability	•		•			•		•		
Standardized work ^a	•	•	•	•	•	•	•	•	•	o
Process confirmation			•			•		•		
Management standard work (MSW)	•		•			•	o	o	o	
Management behavior	•		o	o	o	o	o	o	o	
Visual management ^a	•		•	•	•	•	•	•	o	•
Performance measurement ^a	•	•	•	•	•	•	o	•	•	o
Performance dialogue		o		o				•	•	
Management review		o				o		•	•	
Monitoring and action tracking	o		•							
Change management								•		

• Explicit program element

o Implicit program element

^a Facet of OPEX Management Control dimension (cf. chapter 3.3)

5.2.2 Unintended Consequences of Management Control

To affect SFB for OPEX, managers must avoid or mitigate potential unintended behavioral effects from applying MC. From a structuration perspective, unintended consequences of MC can be explained by production and reproduction of social *interaction*, in which managers can directly engage in (cf. *Figure 20*). Accordingly, the effects from applying MC can affect what MBs are supportive for influencing SFB in the context of OPEX programs. Unintended consequences can therefore be viewed as one critical criterion for identifying supportive MBs. In the following, we elaborate on the unintended effects of MC in the context of pharmaceutical OPEX programs.

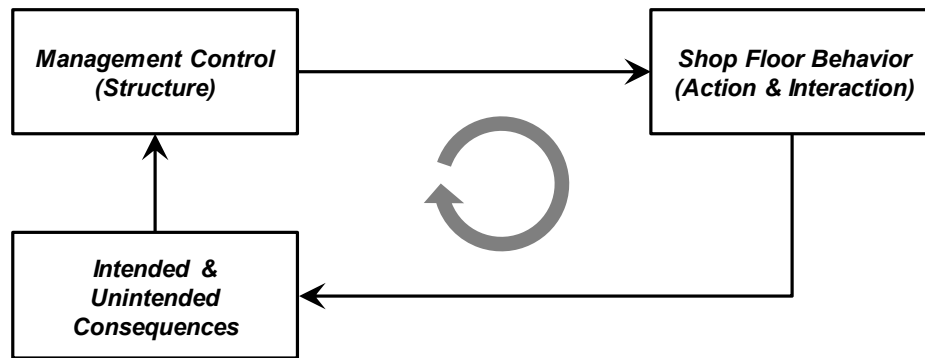


Figure 20: Simplified Management Control Loop, adapted from (Macintosh & Scapens, 1990)

Standardized Work

For our study of unintended effects of the MC dimension *standardized work*, we distinguish between SOPs and standard work. By doing so, we take into account that pharmaceutical companies typically distinguish between the two for regulatory purposes (cf. chapter 5.1).

We find that pharmaceutical manufacturers typically use standard work in addition to SOPs to reduce process variability. In fact, we find that SOPs by itself are based on common practice insufficient for guiding SFB for OPEX. SOPs in pharmaceutical manufacturing are typically written in a way that describes how a specific nominal process looks like. Yet, they typically do not provide operators on the shop floor with further guidance on how to consistently reproduce processes in a way that reduces process variability. To illustrate, SOPs typically specify different process steps as well as parameters for each step that are required to achieve high product quality and comply with regulatory requirements. However, they do not necessarily specify, which of the process steps an operator should do first, whether steps can be done in parallel, or how long it should take to execute each step to get the desired outcomes that satisfy downstream processes. As a result, even in following SOPs, operators will typically conduct steps in slightly different ways. From our empirical research, we find that leaving shop floor personnel with wide room for interpretation on how to best execute processes defined in SOPs is a widespread phenomenon amongst pharmaceutical manufacturers. Since it can cause significant process variability, all operators should perform all process steps defined in SOPs in the same fashion.

The information that puts additional parameters around process steps to guide SFB that go beyond product quality relevant specifications is typically defined as part of standard work. In addition to sequence and time of process steps, standard work could also specify who should conduct a specific process step to ensure optimal process

outcomes. For instance, ‘role 1’ could be responsible for process ‘step A’, whereas ‘role 2’ could be responsible for executing process ‘step B’, ‘step C’ and ‘step D’ in that order concurrently and in predefined times. Nevertheless, the process information defined as part of standard work are typically also limited, since it usually does not specify process aspects that affect product quality to avoid compliance risks. Information related thereto would instead be documented in the SOPs that document how regulatory requirements are met (cf. chapter 5.1).

We identify the parallelism of SOPs and standard work to be a common feature of *standardized work* in pharmaceutical OPEX programs. It is used on the one hand to ensure compliance with regulatory requirements, while on the other hand providing operators with additional information to further harmonize processes across different shifts and work teams. We further find that standard work is limited in its capacity to adequately make up for the lack of in-process guidance of SOPs, since it builds upon existing SOPs and therefore inherit any shortcomings that a respective SOP may have. As a result, we find that the parallelism of SOPs and standard work also comes with a range of unintended consequences for OPEX, which we will outline in the following.

The first unintended effect from *standardized work* in pharmaceutical manufacturing is closely linked to the lack of learning and innovation capabilities. It relates to the broader concept of writing SOPs primarily for regulatory purposes. From an OPEX perspective, *standardized work* should describe the currently best-known way of performing process steps, which should then be updated once a better standard can be defined (cf. chapter 2.1). We find limitations for this concept in pharmaceutical manufacturing in terms of both the regulatory motivation behind SOPs and the effort required to integrate the OPEX objectives with the regulatory objectives. Specifically, we find that shop floor personnel typically do not critically reflect the processes defined in SOPs, since changes to the process are not foreseen during a typical SOP creation phase. This manifests itself in SFB in the form of blindly following procedures, highlighting or escalating problems late or not at all, or working in a reactive mode. Unintended effects of these behaviors include a tendency to hide behind perceived GMP limitations, a general acceptance of the status quo, and a lack of curiosity to solve problems related to efficiency and effectiveness of the processes defined in SOPs.

Unintuitively, another unintended consequence of using standard work additionally to SOPs can be lack of process harmonization. Companies where standard work concepts are in place but are not yet mature report that shop floor personnel tend to come up with individual ‘best ways of working’ that may not always be aligned with different shifts, functions or other organizational entities that are relevant for the respective

process. As a result, shop floor personnel of these companies find themselves relying heavily on SOPs as means to standardize their daily work. Potential reasons include, incomplete roll-out of standard work across a site or production network or immature standard work documents. In order to make up for the lack of adequate work instruction by SOPs, shop floor personnel often develop their individual routines for performing respective processes. We find that when these work routines are developed in an uncoordinated fashion, it can lead to additional variability in the processes. While these individual work routines should not affect product quality and therefore regulatory compliance, as they build upon existing SOPs, they can lead to other unintended performance effects such as increased lead times, scrap or other forms of waste that ultimately affect OPEX. Particularly in process industries such as pharmaceutical manufacturing, where process times often account for the majority lead times, tasks that do not get accomplished within the desired shift or time period can lead to overtimes or increased workloads for subsequent shifts. This can in turn cause frustration among shop floor personnel who must put up extra work or who cannot go home on time, which ultimately affects OPEX.

Finally, the companies report absence of ownership for OPEX in terms of ownership for processes and self-development as direct consequence of the unintended effects outlined above. Given the need to handle *standardized work* and SOPs in parallel, for shop floor personnel it is often not transparent what process improvements are feasible within the regulatory guardrails. Confusion and change aversion are among the unintended consequences of the created ambiguity. We further find that the distinction between SOPs and standard work and associated high effort to implement changes can additionally limit the scope of improvement opportunities for shop floor personnel. Specifically, shop floor personnel are incentivized to limit improvement efforts to those aspects covered by standard work, such as process times and sequence of steps. Everything else is implicitly already earmarked as potentially GMP relevant, that better shouldn't be touched.

Table 25: Unintended behavioral consequences of standardized work

MC Dimension	Purpose for OPEX	Unintended Behavior (UB)	Unintended MC Effects (UME)
<i>Standardized Work</i>	Define currently best-known ways of working to facilitate stable processes and to provide a basis for continuous improvement.	• Blindly following procedures (UB01) • Not exploring new solutions to solve problems (UB02) • Not highlighting or escalating problems (UB03) • Hiding behind perceived GMP limitations (UB04) • Staying in comfort zone (UB05) • Developing individual work routines (UB06) • Controlling standard work in same ways as SOPs (UB07)	• Absence of ownership for process improvement (UME01) • Opaque feasibility of improvements (UME02) • Lack of data-oriented decisions (UME03) • Lack of organizational learning and innovation (UME04) • Lack of harmonized processes (UME05) • Lack of improvement of standards (UME06)

Performance Measurement

MC literatures suggest that *performance measurement* can lead to a range of unintended consequences that, among others, arise from the use and interpretation of KPIs, including selective attention and illusion of control (cf. chapter 3.3.). In the context of impacting SFB with pharmaceutical OPEX programs, we find that the way KPIs are selected and defined depicts an even more relevant root cause of unintended behavioral effects.

The first unintended behavioral effect depicts *disengagement of employees*, which is closely related to the barrier *lack of compelling business need* (cf. chapter 5.1). Many companies have reported difficulties to communicate the benefits of OPEX to shop floor employees. As a result, they often notice that the metrics that are being measured are perceived by shop floor personnel as irrelevant. In addition to this challenge that relates to the purpose of OPEX, companies have identified silo-thinking in combination with highly interconnected value creation processes as another root cause of *disengagement of employees* in OPEX activities related to *performance measurement*. Finally, the studied companies emphasize limitations to making operational changes in the GMP environment as a third potential for *disengagement of employees*. It becomes a challenge for engagement, particularly, when problems become visible through *performance measurement*, but no actions are taking in a timely manner. In these cases, employees get signaled that it is too difficult to eliminate waste, which is therefore acceptable. In the cases outlined above, the studied companies report that *disengagement of employees* manifests itself, among others, in SFB that can be characterized by reporting metrics

that are always ‘green’, lack of reporting at all, or lack of engagement in addressing ‘red’ metrics.

A second unintended consequence related to the selection and identification of KPIs is *working in silos*. Our interviewees found from communication with shop floor personnel that those KPIs that are considered priorities by different areas implicitly set the scope for what is perceived as relevant for OPEX in that area. In turn, OPEX related activities that are outside of this scope are sometimes considered an extra burden that can be perceived as intended top-down control and additional pressure. A possible symptom of this can be a lack of big picture related to OPEX, which can be observed, as the interviewees note, by comments such as ‘this does not apply to our area’ or ‘our area is different’.

Finally, companies have highlighted a tendency in pharmaceutical manufacturing to collect and monitor vast amount of quality relevant data primarily for regulatory purposes. Collecting such data without an immediate operations-focused use case can lead to what is referred to as *paralysis of analysis*. From the expert interviews we find that this can become an issue for OPEX in two ways. On the one hand, respective operational areas have access to comprehensive datasets that could theoretically be used to identify operational improvements instead. The interviewees have noticed that in some cases this can make them question OPEX efforts aimed at monitoring a limited number of KPIs on the shop floor with the objective of making existing types of waste visible daily. Such belittling of OPEX approaches that are intentionally kept simple to enable continual and incremental improvement can be observed particularly well in the natural science-oriented operational areas such as quality functions, that in theory appreciate more technically sophisticated improvement approaches, even though these are rarely applied practice. Possible reasons include lack of incentives, prioritization of firefighting tasks to address existing bottle necks along the value creation process, or high workload. As a result, data that is potentially valuable as part of *performance measurement* is sometimes not used for improvement at all or reduction of identified waste is deprioritized behind other daily priorities and theoretical improvement potential, even though it may not be addressed.

Table 26: Unintended behavioral consequences of performance measurement

MC Dimension	Purpose for OPEX	Unintended Behavior (UB)	Unintended MC Effects (UME)
<i>Performance Measurement</i>	Provide transparency on current performance levels to highlight existing gaps for identifying improvement potential.	• Monitoring of irrelevant metrics (UB08) • Rejecting relevant KPIs as inapplicable (UB09) • Acting in a reactive mode (UB10)	• Perceived pressure (UME07) • Lack of big picture (UME08) • Working in silos (UME09) • Paralysis by analysis (UME10)

Visualization

OPEX aims at making the current state of operations visible in order to facilitate quick decision making and problem-solving. Yet, we find that pursuing this vision in pharmaceutical manufacturing based on *visualization* can lead to connected unintended effects. These include *treating visual systems as GMP structure*, *application on a limited scale*, *resistance to being transparent with metrics*, and *hiding behind the quality system*.

First, in terms of *treating visual systems as GMP structure* and connected to that *application on a limited scale*, we observe that while a maximum level of transparency on the state of operations is traditionally a key objective of OPEX it can complicate the dialogue with regulators in pharmaceutical manufacturing. We find that all studied pharmaceutical companies are very mindful of what information to display on the shop floor based on fears of triggering hard questions from regulators. Possible examples include questions about what specifically happened in instances where performance was below target or potential requests to show that product quality was not affected by incidents that may be visible on visual performance boards. The behavioral consequences of such a perception include at the least hesitance among shop floor personnel about what can be displayed on the boards and in the worst-case employee disengagement. In any case, treating visual boards as GMP structures can limit the ways in which shop floor personnel use visual board for OPEX.

Connected to the unintended effects above, pharmaceutical companies report in some cases *resistance to being transparent with metrics* at visual boards on the shop floor. We find that two separate phenomena can play a role in this observed behavior. On the one hand, there is an ongoing discussion among OPEX experts from pharmaceutical companies about what KPIs, incidents, taken actions and so forth can be displayed on the shop floor without ‘producing’ deviations in the eyes of regulators, which then would need to be processed in accordance with documented procedures. Such a lack of clear guidance can directly affect the way that shop floor personnel perceive and adopt

visualization. On the other hand, visual boards are sometimes perceived as redundant, since all quality relevant data is already tracked for regulatory purposes in more granular levels in quality systems. In situations where shop floor personnel are *hiding behind the quality system* for creating transparency on performance, we find that OPEX managers face difficulties to use *visualization* as a mean to communicate the benefits of tracking and discussing selected metrics daily. Due to existing confusion around regulatory implications from increased transparency on the shop floor and the parallel monitoring of quality relevant data in quality systems, the argument can be made that shop floor personnel are partially incentivized to not fully embrace *visualization* to strive for maximum transparency, as required for OPEX that can ultimately result in an acceptance of the status quo.

In conclusion, we find that different views exist among experts from pharmaceutical manufacturing to what extent their approaches are feasible to cope with the outlined regulatory concerns. While some feel comfortable with their *visualization* approaches and with their dialogue with regulators, others view the topic more as a grey zone. Hence, we find that among the studied companies there is no universal practice on how to optimally implement *visualization* in practice and what aspects to be mindful of when doing so. At the same time, all studied companies recognize, that there is significant potential for confusion, which can act as a barrier for implementing *visualization* on the shop floor.

Table 27: Unintended behavioral consequences of visualization

MC Dimension	Purpose for OPEX	Unintended Behavior (UB)	Unintended MC Effects (UME)
<i>Visualization</i>	Make target state and current process status visible to facilitate timely decision making.	• Treating visual system as GMP structure (UB11) • Application of visual systems on a limited scale (UB12) • Resistance to being open and transparent with visual systems (UB13) • Hiding behind the quality system regarding creating transparency on performance (UB14)	• Lack of visualization and transparency (UME11) • Lack of open dialogue (UME12) • Lack of feedback (UME13) • Lack of organizational learning and innovation (see above)

Employee Empowerment

The purpose of *employee empowerment* is to enable shop floor workers to identify, analyze and address improvement opportunities for OPEX. To achieve this purpose, it involves among others capability building and provision of adequate resources. Yet, despite these positively connotated features of *employee empowerment*, we also find unintended consequences for OPEX in the context of pharmaceutical manufacturing.

The first unintended consequence comprises *lack of proactive management support*. Implementing OPEX in the regulated pharmaceutical environment requires shop floor personnel to have a comprehensive understanding of OPEX, of its cross-section to pharmaceutical regulation as well as of technical operations. Against this backdrop, the companies point out that many of their managers do not fully understand and embrace their role as coaches and facilitators to help shop floor workers integrate all three aspects successfully. We find that in cases where managers do not embrace the role of proactive supporters of shop floor teams, shop floor personnel fall back on established procedures and into silo thinking and don't follow best known ways of working. Examples include proactively ensuring adequate OPEX capability building are in place, or proactively removing roadblocks for shop floor personnel.

The second unintended consequence of *employee empowerment* depicts *misalignment with GMP requirements*. In practice, procedural regulation in pharmaceutical manufacturing limits *employee empowerment*. For instance, not all shop floor workers may be allowed to perform certain tasks. From our study of pharmaceutical OPEX programs it further becomes apparent that organizational implications of working in a regulated environment can conflict with *employee empowerment*. Examples include extensive oversight from quality organization, development of SOPs for regulatory purposes (cf. chapter 5.1) or organizational risk aversion. Shop floor workers can therefore be limited in their abilities to pursue improvement opportunities, which needs to be accounted for as part of OPEX programs. Against this backdrop, we find that *employee empowerment* without accounting for demands placed on OPEX programs by regulatory environment can result in internal and external pushbacks for shop floor personnel. These include potential pushbacks from the quality organization, from regulatory auditors, or from line managers. These pushbacks can have unintended behavioral implications for shop floor workers that can ultimately result in disengagement of shop floor workers in OPEX. Potential unintended behaviors include staying in comfort zone to avoid resistance from the quality organization, distrusting leadership of OPEX program, or not taking ownership for improvements.

The third notable unintended consequence of *employee empowerment* that we identify depicts *limited handover of accountability*. It is primarily critical from a compliance perspective. However, since pharmaceutical OPEX programs take place in a regulatory environment, we find that it also has unintended behavioral implication for OPEX. Many of the studied companies state that their managers have difficulties giving up control to shop floor workers, which by itself is not specific to managers in pharmaceutical manufacturing. However, we find that in pharmaceutical manufacturing accountability for processes also has regulatory implications. Accountability for processes is typically linked to the hierarchical structure, as processes potentially need to be documented and controlled as part of the companies GMP system (cf. chapter 5.1). We find that being required to handover of accountability to shop floor personnel can in fact be viewed as an unintended consequence of OPEX from the perspective of a manager in pharmaceutical manufacturing. As a direct consequence of managers not letting go of control, unintended SFB from *employee empowerment* can thus include not taking ownership for CI.

Table 28: Unintended behavioral consequences of employee empowerment

MC Dimension	Purpose for OPEX	Unintended Behavior (UB)	Unintended MC Effects (UME)
<i>Employee Empowerment</i>	Enable work force to identify, analyze and address improvement opportunities for OPEX on their own.	• Falling back on established procedures (UB15) • Not following best known ways of working (UB16) • Intervening quality organization (UB17) • Working in silos (UB18) • Staying in comfort zone (UB19) • Distrusting leadership of OPEX program (UB20) • Not taking ownership for continuous improvement (UB21) • Not letting go of control (UB22)	• Lack of proactive management support (UME14) • Misalignment with GMP requirements (UME15) • Internal or external resistance (UME16) • Limited handover of accountability (UME17)

Training

Training aims at providing shop floor workers with sufficient OPEX knowledge to deploy relevant aspects of the companies OPEX program in desired ways. Unintended consequences of *training* include *mismatch with daily work and needs*, *lack of management support* and *inconsistent levels of proficiency*.

The most stated unintended effect of *training* depicts *mismatch with daily work and needs*. Adequate capability building on shop floor level depicts a key challenge for the studied companies. We find both overcoaching and undercoaching to be unintended MBs. In this context, undercoaching refers to *training* that is inadequate for enabling shop floor workers to fulfill OPEX related management expectations. In contrast, overcoaching, refers to providing shop floor personnel with extensive *training* support when in fact other forms of management support would be needed. Examples include situations that are characterized by conflict between different relevant stakeholders, which require decision making or escalation by management.

Inconsistent levels of proficiency depict the second source of unintended effect of *training*. Influencing factors that contribute to this unintended effect can be manifold. Examples that we identified include employee fluctuation, heterogenous levels of qualification of trainers as well as trainees, or lack of resources to conduct business relevant training as opposed to generic classroom training. Behavioral implications related to *inconsistent levels of proficiency* include judging colleagues and not letting go of control by management.

The third unintended consequence of *training* depicts *lack of management support*. Many companies state that in the past, *training* was a one-time effort that was not followed up upon by further management assistance. As a result, *training* approaches overemphasized transmitting information to the neglect of supporting shop floor personnel in applying acquired knowledge. As a result of *lack of management support*, both future coaches and other shop floor personnel are often left unprepared for future OPEX related tasks.

Table 29: Unintended behavioral consequences of training

MC Dimension	Purpose for OPEX	Unintended Behavior (UB)	Unintended MC Effects (UME)
<i>Training</i>	Provide employees with sufficient OPEX knowledge to deploy relevant aspects of the OPEX program in desired ways.	• Undercoaching (UB23) • Overcoaching (UB24) • Judging colleagues (UB25) • Not letting go of control (UB26) • Overemphasizing transmitting information to the neglect of supporting shop floor workers (UB27) • Focusing on certification (UB28) • Overemphasizing prior knowledge and assumptions (UB2X9) • Using training for punitive purposes (UB30) • Paralysis from complexity of situation (UB31)	• Mismatch with daily work and needs (UME18) • Inconsistent levels of proficiency (UME19) • Lack of proactive management support (see above) • Overextension of employees (UME20) • Loss of motivation (UME21) • Frustration (UME22)

Goal Setting

The purpose of *goal setting* is to translate corporate strategic priorities into measurable goals on shop floor level. In practice, goals are set in the studied OPEX programs top-down and in the form of KPI targets or specific tasks. Goals are then cascaded down vertically from corporate level across hierarchical levels to lower levels, including site, area, team and individual level, based on sophisticated *goal setting* concepts. While *goal setting* theoretically is not limited to vertical alignment and can also include horizontal alignment across different functional area, we find that the latter plays a subordinate role in *goal setting* concepts of pharmaceutical OPEX programs.

Our research suggests that *goal setting* can lead to a range of unintended effects in pharmaceutical OPEX programs that can conflict with the purpose outlined above. Unintended consequences include among others *dissociation of the shop floor*, *perceived pressure*, *lack of big picture*, *goal ambiguity*, and *disempowerment*, which we will outline in the following.

We find that *dissociation of the shop floor* from pharmaceutical OPEX program, can be a result of conflicting messages sent to shop floor workers as part of *goal setting*. Objectives set explicitly in the context of pharmaceutical OPEX programs can overlap with other potentially conflicting goals that are formulated implicitly. Examples include implicit goals formulated by cross-functions or supervisors, that can ultimately deter shop floor personnel from pursuing OPEX objectives. Examples include expectations implicitly formulated by the quality organization due to its oversight function. To illustrate, we find that interventions from quality organizations in shop floor activities represent a common theme among pharmaceutical OPEX programs that can set implicit goals for shop floor personnel. In case of compliance concerns, shop floor personnel are exposed to scrutiny from the quality organization when pursuing OPEX objectives. For example, PharmaCo A reports instances of shop floor workers developing ideas for continuous improvement, only to be stopped from finally implementing them by the quality organization based on compliance concerns. The company claims that in such situations, shop floor personnel are likely to prioritize expectations of the quality organization over explicit objectives set as part of *goal setting*. The rationale behind it is that the quality organization is ultimately accountable for product quality and, thus, for all aspects of production that can have an impact on it. Accordingly, the quality organization typically has the authority to overrule decisions of shop floor personnel, even though it is separated from the OPEX organization (cf. chapter 5.1). Since quality and compliance concerns can reach into most aspect of the manufacturing operations, the company further points out that it does not even require interventions from the

quality organization to deter shop floor workers from pursuing OPEX goals. Instead, shop floor personnel can already be deterred from pursuing OPEX when they perceive goals to be not fully aligned with expectations of the quality organization. Another factor that can keep shop floor workers from pursuing OPEX objectives includes sanctioning of deviations from goals by superiors. The studied companies are very cautious, not to react to deviations from targets in ways that are perceived by shop floor personnel as punishing. Calling out shop floor areas based on poor performance is a practice that all studied companies emphasize to be counterproductive.

Related to the issue of organizational misalignment is the issue of *perceived pressure*. The studied companies highlight different factors that can build up *perceived pressure* for shop floor personnel. Notable examples include perceived regulatory uncertainty (cf. chapter 5.1), setting unrealistic goals or conflicting priorities such as in the example outlined above. All of these have in common that they make the pathway for how to achieve OPEX in alignment with organizational priorities less clear for shop floor personnel. It can manifest itself in SFB in the form of not expressing concerns or by focusing on the wrong problems, which ultimately result in *perceived pressure*. Because of *perceived pressure*, shop floor workers are more likely to experience *frustration* over OPEX initiatives and are less likely to go beyond what is required, which can ultimately hinder organizational learning and innovation.

A third unintended effect of *goal setting* depicts *lack of big picture*. Most of the studied companies point out that they have difficulties to set a clear direction for shop floor personnel on how to achieve OPEX in alignment. With reference to OPEX as a journey, this is also described as a lack of ‘true north’ of OPEX programs. As a potential root cause, companies state that the complex nature of cause-and-effect relationships between OPEX levers and performance outcomes makes it difficult to provide shop floor personnel with clear guidance how to achieve OPEX. Further potential root causes include optimization against moving targets based on perceived regulatory uncertainty or lack of data-orientation. Unintended behavioral consequences of this challenge include focusing on the wrong problems in terms of OPEX, difficulty to communicate benefits of OPEX tasks. Further behavioral implications include setting unrealistic goals that are not aligned with reality on the shop floor, setting too many goals to account for different organizational priorities, inadequately prioritizing goals, or setting goals with a too strong focus on the ‘how?’ instead of ‘what?’.

Goal ambiguity represents a third unintended effect that can prevent shop floor personnel from pursuing OPEX. We find that setting goals as part of OPEX that are consistent with each other depicts a challenge for many pharmaceutical manufacturers.

We find that compliance objectives and objectives related to other aspects of operational performance are in fact treated as conflicting objectives in pharmaceutical OPEX programs (cf. chapter 1.1). We further find that when in doubt, the studied pharmaceutical companies usually prioritize compliance objectives over other operational objectives, given the severe consequences that non-compliance can have on business performance (cf. chapter 5.1). Yet, compliance and other OPEX objectives are not conceptualized as standing in conflict with each other in either of the studied OPEX programs. In fact, all studied OPEX programs set out to help achieve and sustain regulatory compliance, while simultaneously improving operational performance in other relevant dimensions, such as delivery performance or cost. Against this backdrop, we find that, in practice, compliance and other aspects of OPEX are treated in practices as trade-offs, despite internal communication that is more aligned with cumulative views. As a result, shop floor personnel, in practice, have the task to achieve holistic improvement while in facing a practical trade-off situation. In these situations, it can be unclear how goals can be achieved and how they should be prioritized. Examples include goals to increase performance that may require changes in the GMP environment. While it may not be a conflict by itself, the implementation of changes can result for shop floor workers in conflicting priorities in practice. As factors that can cause conflicting objectives in practice, we identify among others a lack of adequate communication or dialogue on goals or lack of required capabilities of shop floor personnel.

Finally, we discover a tendency for micromanagement in pharmaceutical OPEX programs that establishes a link between *goal setting* and a lack of *employee empowerment*. Finding a balance between autonomy of shop floor teams on the one hand top support OPEX and risk avoidance on the other hand poses a challenge for the studied companies. Thus far, none of the studied companies has fully transitioned from command-and-control type management to more autonomous teams, even though all aspire to do so. PharmaCo C, for instance, is currently encouraging shop floor workers to move away from taking orders to taking more ownership for improvement of the processes that they are working on. At the same time, the company highlights a need for what it refers to as ‘guided autonomy’ to guardrail SFB. It therefore plans to continue to keep shop floor workers under close supervision by accountable managers, while intending to increase responsibilities of shop floor workers. Similarly, the other studied companies expect shop floor personnel to take ownership for holistic performance improvement, while simultaneously striving for narrow guidance of shop floor personnel to ensure regulatory compliance.

Table 30: Unintended behavioral consequences of goal setting

MC Dimension	Purpose for OPEX	Unintended Behavior (UB)	Unintended MC Effects (UME)
<i>Goal setting</i>	Providing employees with a clear and engaging direction for continuous improvement that focuses attention on a common goal and that motivates.	• Intervening in shop floor activities (UB32) • Neglecting OPEX objectives (UB33) • Micromanaging shop floor activities (UB34) • Sanctioning of deviations from goals (UB35) • Focusing on wrong problems (UB36) • Setting unrealistic goals (UB37) • Not expressing concerns (UB38)	• Dissociation of shop floor (UME23) • Lack of organizational learning and innovation (see above) • Perceived pressure (see above) • Frustration (see above) • Lack of big picture (see above) • Goal ambiguity (UME24) • Disempowerment (UME25)

Conclusion

By studying unintended effects of each of the six MC dimensions, empirical insights into the behavioral implications of MC in pharmaceutical OPEX programs are obtained. The identified effects are particularly relevant for this specific research context. Yet, they may in parts also be relevant for OPEX programs of companies from industries other than pharmaceutical manufacturing.

The findings illustrate the manifold ways in which unintended MC effects can manifest through interaction between MC and different actors. Notable groups of actors in this research context include shop floor personnel, their supervisors, members of support functions, such as the quality organization, or representatives of regulatory authorities. The interplay between MC and the behavior of actors involved therefore affect the engagement of shop floor personnel in OPEX in conjunction. Examples include interventions from quality personnel or from the regulatory body that can have broader implications for organizational behavior, which can ultimately affect SFB.

Related to that, this research suggests that while existing OPEX literature emphasizes the role of MB for influencing SFB, it falls short of capturing other relevant behavioral aspects. Potential reasons for that include its focus on the intended behavior of individual managers. In this regard, this findings suggest that existing literature lacks adequate considerations of interrelations between MC, MB as structural and behavioral aspects of OPEX programs. As outlined above, it further shows how the behavior of different groups of organizational members needs to be considered when interpreting the behavioral implications of MC. Accordingly, behavioral implications of MC should

be analyzed under consideration of the organizational context, including all relevant actors that engage knowingly or unknowingly in the process of exerting MC.

Next, the findings suggest that the pharmaceutical GMP environment can amplify unintended consequences from MC, as it places additional demands on organizational behavior. As outlined in this chapter, procedural regulation can lead to several potentially counterproductive effects that can be viewed as limiting factors for OPEX engagement of shop floor personnel. On the other hand, no empirical evidence for beneficial behavioral effects from procedural regulation are found from an OPEX perspective. As a result, pharmaceutical companies should take procedural regulation into account in order to circumvent potential unintended effects of MC.

Finally, the identified unintended MC effects allow deriving associated behavioral mechanisms that affect SFB. From reviewing the unintended effects of each MC dimension, six underlying behavioral mechanisms of SFB can be derived (cf. *Table 31*).

The largest number of unintended effects is at least partially associated with the behavioral mechanism *motivation*. Based on the findings from this chapter, each of the six MC dimensions can have unintended effects that negatively affect the *motivation* of shop floor personnel. Since participation of shop floor workers is a key prerequisite for OPEX, researchers and practitioners should pay close attention to the effects that MC has on the *motivation* of shop floor personnel. Similarly, all MC dimensions can have unintended MC effects that relate to a lack of *enablement*. While *motivation* affects the willingness of shop floor personnel to adopt OPEX, *enablement* is viewed as affecting their capabilities to act in intended ways. Therefore, for this research it is concluded that all MC dimensions can potentially significantly hinder intended SFB, in case the unintended effects result in a lack of *motivation* of shop floor personnel respectively in a lack of *enablement*. Other behavioral mechanisms that are associated with the unintended MC effects include *discipline*, *goal alignment*, *data-orientation* and *accountability*. Each mechanism is only associated with the unintended effects of subsets of the six MC dimensions. Thus, not all MC dimensions affect all of these behavioral mechanisms. Finally, it is worth highlighting that the identified unintended MC effects can be associated with multiple underlying behavioral mechanisms. The unintended effect *lack of harmonized processes*, for example, can affect both *enablement* and *discipline* of shop floor personnel. On the one hand, it can result in a lack of a common basis for improvement for shop floor workers to build upon, and thus in a lack of *enablement*. On the other hand, unharmonized processes pose a practical challenge for monitoring standard adherence, which can in turn lead to a lack of *discipline*.

Table 31: Underlying behavioral mechanisms of unintended MC consequences

MC Dimension	Unintended MC Effects (UME)	Enablement	Motivation	Discipline	Goal alignment	Data-orientation	Accountability
Standardized work	• Absence of ownership for process improvement (UME01)		•				•
	• Opaque feasibility of improvements (UME02)	•				•	
	• Lack of data-oriented decisions (UME03)					•	
	• Lack of organizational learning and innovation (UME04)	•	•	•		•	
	• Lack of harmonized processes (UME05)	•		•			
	• Lack of improvement of standards (UME06)		•				
Performance measurement	• Perceived pressure (UME07)		•				
	• Lack of big picture (UME08)		•		•		
	• Working in silos (UME09)	•			•		•
	• Paralysis by analysis (UME10)	•					
Visualization	• Lack of visualization and transparency (UME11)				•	•	
	• Lack of open dialogue (UME12)				•	•	
	• Lack of feedback (UME13)	•	•	•	•		
	• Lack of organizational learning and innovation (see above)	•	•	•		•	
Employee Empowerment	• Lack of proactive management support (UME14)	•					
	• Misalignment with GMP requirements (UME15)		•	•	•		
	• Internal or external resistance (UME16)		•				
	• Limited handover of accountability (UME17)	•	•				•
Training	• Mismatch with daily work and needs (UME18)	•	•	•			
	• Inconsistent levels of proficiency (UME19)	•					
	• Lack of proactive management support (see above)	•					
	• Overextension of employees (UME20)	•	•				
	• Loss of motivation (UME21)		•				
	• Frustration (UME22)		•				
Goal setting	• Dissociation of shop floor (UME23)		•		•		
	• Lack of organizational learning and innovation (see above)	•	•	•		•	
	• Perceived pressure (see above)		•				
	• Frustration (see above)		•				
	• Lack of big picture (see above)		•				
	• Goal ambiguity (UME24)		•		•		•
	• Disempowerment (UME25)	•	•				

5.2.3 Intended Management Behaviors

To identify supportive MBs for impacting SFB, the MBs that are intended by OPEX experts of the analyzed pharmaceutical companies are studied. In order to qualify as a supportive MB, a MB should contribute to facilitating relevant aspects of the envisioned SFB. In this research, the intended SFB corresponds to the intended behavioral effects of MC (cf. *Table 12*).

To evaluate the identified MBs in terms of supportiveness for impacting SFB, the behavioral effects of MC are conceptually distinguished by effect and by intention. As a result, two categories of MC effects are obtained (cf. *Figure 21*), one or both of which each of the identified MBs should address, in order to qualify as supportive in this research context. The first category represents the unintended and counterproductive effects derived in chapter 5.2.2, which should be mitigated or eliminated. The second category depicts intended beneficial effects of MC (cf. chapter 3.3), which should be strengthened. The other two categories are not in the focus of this research for separate reasons. To illustrate, the third category covering beneficial, yet unintended effects can, by definition, only unintentionally be taken advantage of, while the fourth category is not applicable for the context of OPEX programs.

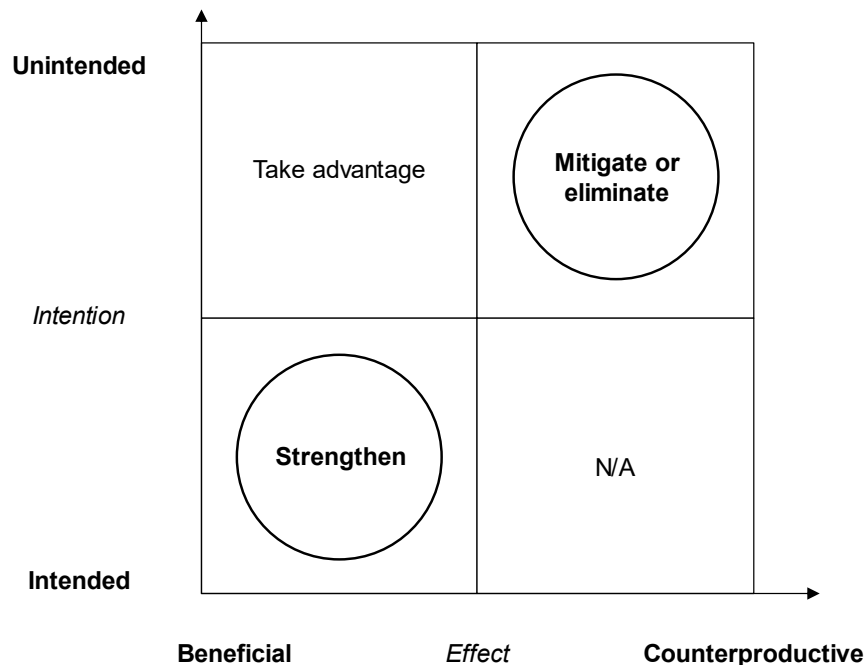


Figure 21: Categories of Management Control effects to be addressed by MB

The empirical analysis suggests that most of the studied OPEX programs explicitly or implicitly expect managers to act in certain ways to support OPEX. The identified intended MBs that will be presented in the following can be clustered into thirteen categories along the three dimensions of the structuration theory, namely

communication, *sanction* or *power*. *Communication* represents the primary purpose for four of the thirteen MB categories. These behaviors are referred to as *communication-focused* MBs, following (Giddens, 1979), who suggests that *communication* does not take place outside of *power* relations or *sanction* and vice versa (cf. chapter 3.1). Analogously, we refer to four MB categories as *power-focused*, and to the remaining three as *sanction-focused*.

In the following sections, we elaborate for each dimension of MBs on both intended effects and on the addressable unintended MC effects. In order to derive the latter, first, the behavioral mechanisms that underly the intended effects of the identified MB are identified. Based on these behavioral mechanisms, addressable unintended effects are derived for each identified MB on a case-by-case basis. For this purpose, we consider both the previously established link between relevant aspect of intended SFB and MC dimension (cf. *Table 12*) as well as the behavioral mechanisms that are associated with the unintended effects of MC (cf. *Table 31*). By drawing on both inputs, we can finally narrow down the set of relevant unintended effects by source, in terms of underlying MC dimension, and by associated behavioral mechanism.

5.2.3.1 *Intended Communication-focused Management Behaviors*

The identified *communication-focused* MBs suggest that managers play a critical role for impacting SFB as communicators. In sum, we identify 16 intended *communication-focused* MBs for impacting SFB, which we structure them along the four sub-categories *cascading strategy*, *role modelling*, *uncovering guidelines* and *instilling improvement mindset* (cf. *Table 32*). The identified MBs from this dimension intend to facilitate the desired SFBs *identifying improvement opportunities*, *adhering to standards*, *acting on improvement opportunities*, *fact-based decision making*, and *highlighting issues that require escalation*, which we will elaborate on in the following in more detail.

Table 32: Communication-focused Management Behavior

Sub-Category	Management Behavior (MB)	Intended SFB	Effect Mechanism	Addressable Unintended MC Effect (UME)
<i>Cascading Strategy</i>	Provide clear guidance on what should be achieved on a daily base (MB01)	Identifying improvement opportunities	Goal alignment, enablement, motivation	UME14, UME16
	Make expectations transparent (MB02)			UME01-02, UME08, UME18-19, UME25
	Consistently explain the reason behind OPEX program elements (MB03)			UME20, UME23-E24
<i>Role Modelling</i>	Be coherent to guiding OPEX principles (MB04)	Adhering to standards, highlighting issues that require escalation, acting on improvement opportunities, fact-based decision making, identifying improvement opportunities	Discipline, goal alignment, enablement, motivation, data-orientation	UME02, UME04, UME20, UME24
	Always follow through on OPEX commitments (MB05)			UME24
	Showcase the desired behaviors (MB06)			UME02, UME13, UME25
	Adhere to MSW (MB07)			UME17, UME20, UME21, UME23
	Act with immediate responsiveness (MB08)			UME24
<i>Uncovering Guidelines</i>	Make OPEX commitment visible (MB09)			UME23-24
	- Routinely ask for SOP reference (MB10) - Base decisions on data (MB11)	Fact-based decision making	Discipline, data-orientation	- UME01-04, UME11 - UME09
<i>Instilling Improvement Mindset</i>	Create a sense of urgency (MB12)	Acting on improvement opportunities, fact-based decision making	Motivation, data-orientation	UME04, UME08, UME23-24
	Create enthusiasm based on ambitious targets (MB13)			UME08, UME23-E24
	Routinely ask for data (MB14)			UME02-04, UME09, UME11
	- Show equal commitment to OPEX and to compliance (MB15) - Encourage calculated risk taking and learning from failure (MB16)			UME02-04, UME15

Effects on Intended Shop Floor Behavior

Identifying improvement opportunities

Many of the studied companies report difficulties to involve shop floor personnel in the process of independently identifying improvement opportunities. To formulate and communicate a convincing rationale for continuous improvement that resonates with shop floor personnel, they emphasize, among others, the importance of MBs related to *cascading strategy* down to shop floor level. Inability to communicate a convincing business need can therefore be viewed as a potential barrier for OPEX.

To enable shop floor personnel to identify improvement opportunities that matter from a corporate perspective, the analyzed companies suggest that managers should provide clear guidance on what must be achieved. To achieve this task, the intended MBs include communicating their expectations.

Adhering to standards

The identified MBs acknowledge the importance of adherence of SFB to standards, such as defined in SOPs. Such adherence is critical both for OPEX and for compliance, since both rely on stable and reliable processes.

The intended MBs suggest that *role modelling* depicts a critical MB for ensuring that shop floor personnel follow standards. On the one hand, MBs related to *role modelling* allow managers to demonstrate OPEX commitment. It further allows them to demonstrate that they follow OPEX-related standards themselves, which can help instill discipline among shop floor personnel to follow standards, likewise. It can also provide shop floor personnel with guidance how to conduct themselves to support the company's OPEX program by showcasing desired behaviors in situations where standard processes are not available. Examples include continuous improvement and problem-solving activities. Finally, managers that demonstrate OPEX commitment through acting immediately on issues can help communicate a sense of urgency that can help claim similar discipline from shop floor personnel.

Highlighting issues that require escalation

In addition to supporting identification of improvement opportunities and adherence to standards, *role modelling* can encourage shop floor personnel to highlight issues that require escalation. As underlying behavioral mechanisms, we identify instilling discipline as well as enabling shop floor personnel. To illustrate, *role modeling* can contribute to demonstrating management commitment to OPEX, which can in turn

increase discipline of shop floor workers to highlight issues that require management attention. In a similar vein, *role modelling* can be applied to showcase the desired behaviors, which can in turn contribute to intended SFB through enhanced enablement of shop floor personnel and goal alignment in terms of desired target behaviors.

Acting on improvement opportunities

In addition to instilling discipline, *role modelling* of adequate OPEX conduct is also viewed by the studied companies as a mean for inspiring and motivating shop floor personnel to act on improvement opportunities. In addition to the importance of *role modelling* desired SFB, the studied companies emphasize the need for managers to act in ways that are coherent to guiding OPEX principles.

Similarly, the identified MBs related to *instilling improvement mindset* can have a positive impact on the motivation of shop floor workers to act on improvement opportunities. Intended MBs include, creating a sense of urgency or setting ambitious and inspiring targets to create enthusiasm among shop floor workers. To further motivate them to act on opportunities, managers should further demonstrate equal commitment to both OPEX and compliance. Likewise, acting on improvement opportunities can potentially be promoted by encouraging calculated risk-taking. While pharmaceutical manufacturers operate in a risk averse environment, calculated risk-taking is viewed by some experts as an antidote to change aversion on the shop floor. PharmaCo A suggests that shop floor workers are more likely to act on improvement opportunities, when they receive management support. In turn, managers are more likely to support improvement ideas, when they can draw on data to make risk-based decisions. Encouraging calculated risk-taking could signal general management support, while motivating shop floor personnel to provide managers routinely with relevant analysis to facilitate decision-making. In conjunction, both could therefore increase the likelihood shop floor personnel acting on identified improvement opportunities.

Fact-based decision making

Another intended effect of the identified MBs depicts fact-based decision making. According to OPEX experts from PharmaCo E, intended MBs from the subcategories *uncovering guidelines* and *instilling improvement mindset* can facilitate this aspect of intended SFB.

The MBs related to *uncovering guidelines* can, for example, facilitate fact-based decision making by revealing or substantiating assumed or implicit guidelines for relevant activities. On the one hand, routinely asking for SOP reference represents an

effective way to address concerns of shop floor personnel regarding potential regulatory constraints for intended improvements. By encouraging shop floor personnel to specify their concerns based on SOPs, managers can facilitate fact-based decision making in situations where uncertainty regarding regulatory requirements exists.

In terms of *instilling improvement mindset*, routinely asking for data is identified as an intended MB that can help encouraging fact-based decision. Like the intended MB asking for SOP reference, asking for data more broadly requires workers to prepare and make decisions based on data that can be evaluated by other members of the organization.

Addressable Unintended Management Control Effects

The identified MBs can contribute to addressing unintended MC effects that are associated with the underlying behavioral mechanisms motivation, goal alignment, discipline, enablement, and data orientation.

Routinely asking for data can, for example, help address opaque feasibility of improvements (UME02) and lack of organizational learning and innovation (UME04) by creating transparency on the criticality of an assumed opportunity. While data-orientation can be considered helpful for organizational improvement initiatives in any industry, it is particularly critical for creating a sense of urgency in order to justify complex changes in the regulated pharmaceutical environment. As PharmaCo G emphasizes, operational changes that affect a validated area of production can require significant effort. Improvement opportunities are therefore sometimes not pursued, due to the assumed high effort required. However, when the criticality of an opportunity can be legitimized based on data, PharmaCo G suggests that its management is more likely to recognize the urgency of a potential issue, and to commit resources to solving the issue in a timely manner.

Another example of how the identified *communication*-focused MBs can address unintended MC effects involves goal alignment and coherence to guiding OPEX principles. According to PharmaCo A, managers sometimes behave in ways that are incoherent with OPEX principles, which can therefore potentially hinder the adoption of intended SFB. Examples include circumventing any potentially compliance relevant area during improvement activities, or hiding behind the quality organization, in situations where it is unclear whether potential improvements are compliance relevant or not. Further examples include micromanagement and control tendency of supervisors, since in pharmaceutical manufacturing, supervisors are typically accountable for ensuring that the operations they oversee are compliant with regulatory requirements.

The identified MBs being coherent to guiding OPEX principles (MB04) or making OPEX commitment visible (MB09) from subcategory *role modelling* can contribute to increased goal alignment based on increased coherence of MB with OPEX principles. As a result, they can contribute to addressing unintended MC effects such as lack of organizational learning and innovation (UME04), or dissociation of shop floor (UME23).

5.2.3.2 *Intended Power-focused Management Behaviors*

In addition to adequate communication of the OPEX program, the findings suggest that managers should, through their own behavior, comprehensively manage the *power*-relations that affect the shop floor personnel's ability to adopt intended SFBs. In total, we identify 20 intended *power*-focused MBs that can play a critical role for managing relevant aspects of *power*-relations in the context of pharmaceutical OPEX programs. They can be clustered into five categories, which can be viewed as behavioral levers for what is commonly referred to in the context of OPEX programs as employee empowerment. These include *building capability*, *simplifying*, *addressing problems*, and *resolving ambiguities* (cf. Table 33).

Both the previously introduced *communication*-focused MBs and the intended *power*-focused MBs can support the intended SFBs *identifying improvement opportunities* and *acting on improvement opportunities*. In terms of these aspects of intended SFB, the *power*-focused MBs can therefore be viewed as supplementing *communication*-focused MBs. In addition, the identified *power*-focused MBs can contribute to *timely and independent decision making*, *fact-based decision making*, and *highlighting issues that require escalation*.

Table 33: Power-focused Management Behaviors

Sub-Category	Management Behavior (MB)	Intended SFB	Effect Mechanism	Addressable Unintended MC Effect (UME)
<i>Assigning Accountability</i>	• Cascade decision making to levels closest to workplace (MB17)	Timely and independent decision making, highlighting issues that require escalation	Enablement, motivation, discipline, accountability	• UME01, UME17, UME20
	• Be approachable on the shop floor (MB18)			• UME04, UME18, UME21
	• Provide a clear pathway for integrating OPEX and compliance objectives (MB19)			• UME02, UME08-E09, UME14, UME15, UME18, UME22-23
	• Fosters inclusivity of thought and action (MB20)			• UME01, UME04
	• Engage in macro management (MB21)			• UME01, UME04, UME17
<i>Building Capability</i>	• Act as a coach rather than a supervisor (MB22)	Identifying improvement opportunities,	Enablement, motivation	• UME02, UME13, UME16-18
	• Provide frequent coaching support in the process (MB23)	timely and independent decision making, acting on improvement opportunities		• UME01-02, UME04, UME07, UME13, UME16, UME18, UME22
	• Support colleagues to unlock potential (MB24)			• UME01-02, UME04, UME07, UME18, UME20, UME22, UME25
<i>Simplifying</i>	• Share successful practices (MB25)			• UME01, UME14, UME19
	• Translate organizational priorities into goals for daily work (MB26)	Identifying improvement opportunities,	Goal alignment,	• UME08
	• Anticipate and remove roadblocks and simplify daily work (MB27)	timely and independent decision making,	enablement, motivation, accountability	• UME01-02, UME04, UME07, UME15-16, UME22-23
	• Encourage shop floor personnel to challenge standardized work documents (MB28)	acting on improvement opportunities		• UME04, UME15-16, UME22, UME25
	• Assign role-based tasks (MB29)			• UME01-02, UME04, UME07, UME15-16, UME19, UME22
<i>Addressing Problems</i>	• Leverage problems as opportunities for making changes (MB30)	Acting on improvement opportunities,	Motivation, enablement	• UME01-02, UME04, UME09-10, UME15, UME21
	• Eradicate problems rather than containing them (MB31)	highlighting issues that require escalation		• UME04, UME09, UME15-16
	• Act decisively on issues (MB32)			• UME04, UME13, UME22, UME25
<i>Resolving ambiguities</i>	• Adjust expectations to guiding OPEX principles (MB33)	Acting on improvement opportunities,	Motivation, enablement	• UME15
	• Set an emphasis on customer needs beyond compliance (MB34)	highlighting issues that require escalation		• UME08-09
	• Translate vague principles into unambiguous guidance (MB35)			• UME16, UME23-24
	• Embrace problems as opportunities for engaging with shop floor personnel (MB36)			• UME01

Effects on Intended Shop Floor Behavior

Identification of improvement opportunities

Capability building and *simplifying* represent two subcategories of *power-focused* MB that experts from the studies companies draw from for empowering shop floor personnel to identify improvement opportunities independently. The behaviors from the former subcategory focus on enabling and motivating shop floor personnel through regular coaching and successful practice sharing. MBs related to the latter, on the other hand, focus on the behavioral mechanisms goal alignment, enablement, motivation, and accountability.

In terms of simplifying, our findings suggest that managers play a crucial role for reducing complexity and for avoiding ambiguity as part of OPEX programs. Among others, managers should adopt the role as enablers by simplifying the complex interdependencies as part of OPEX programs. To illustrate, due to the separation of quality from OPEX organization, the studied pharmaceutical companies often implicitly differentiate between a so-called quality culture and OPEX mindset. These subcultures can require different behaviors, which are not always easily distinguishable from the perspective of shop floor personnel. Both the quality system and the OPEX organization further require shop floor personnel to follow their methods and principles, which may not always have aligned guiding principles. Against this backdrop, managers should anticipate and remove roadblocks and simplify daily work (MB27). By doing so, they can encourage shop floor personnel to seek improvement opportunities, while maintaining a quality culture.

Acting on improvement opportunities

The identified MBs address enablement, motivation and accountability as behavioral mechanisms for supporting workers to act on improvement opportunities. Overall, MBs in four of the six derived subcategories are identified that can support respective intended SFB. These include *building capability*, *resolving ambiguities*, *addressing problems*, and *simplifying*.

To improve levels of engagement in improvement activities, managers should, for example, assign role-based tasks (MB29). As one interviewee points out, in pharmaceutical manufacturing improvement activities can in practice sometimes not be performed by every worker, for example, because they may not be admitted executing certain procedures or to access certain areas of production. Examples include procedures

that require prior training to be compliant, or production areas with increased contamination precautions. By defining role-based tasks, workers can be empowered by enabling them to focus efforts on tasks they can properly fulfill. Additionally, it can help maintain employee motivation, by reducing the risk of frustration and overburdening from tasks that are not feasible.

Timely and independent decision making

As the main mechanism for facilitating timely and independent decision making, enablement is identified. Based on the identified MBs, the three subcategories *assigning accountability*, *building capability* and *simplifying* can all contribute to this facet of intended SFB.

Due to the control tendency of supervisors in pharmaceutical manufacturing for compliance purposes, engaging in macro management (MB21) is viewed as lever for facilitating the intended SFB. Specifically, managers should provide workers with enough competencies to make decisions on a limited scale. Since making such decisions requires not only sound operational capabilities but also OPEX understanding, this requires among others regular coaching support. Managers should, therefore, be approachable on the shop floor (MB18) and they should further act as coaches, as suggested by the MBs from subcategory *building capabilities*.

Highlighting issues that require escalation

For empowering workers to highlight relevant issues, *assigning accountability*, *addressing problems*, and *resolving ambiguities* are identified as relevant subcategories of intended *power-focused* MBs. By addressing the behavioral mechanisms enablement and motivation, each subcategory can contribute to increased employee awareness for OPEX related issues.

As an exemplary MB for facilitating the intended SFB, eradicating problems rather than containing them is identified (MB31). Based on this MB, managers can signal a sense of urgency for making operational improvements. Among others, this can contribute to increased awareness of shop floor personnel for operational deficiencies, by signaling OPEX related ambitions. This can include ambitions to overcome potential change aversion. In addition, it can strengthen enablement and motivation of workers, by signaling commitment to operational improvement.

Addressable Unintended Management Control Effects

Enablement can be viewed as a central behavioral mechanism that underlies all identified subcategories of *power*-focused MBs. Specifically, all subcategories include intended MBs that can contribute to enablement of shop floor personnel. The identified *power*-focused behaviors are therefore favored to address unintended MC effects associated with lack of enablement. Based on the identified underlying behavioral mechanisms of the intended SFBs, they can additionally address unintended effects related to lack of motivation, discipline, accountability, or goal alignment.

In addition to the potential of the *power*-focused MBs for a mitigating lack of proactive management support (UME04), Lack of feedback (UME13), or overextension of employees (UME20), an exemplary unintended effect that can be addressed includes opaque feasibility of improvements (UME02). The identified MBs provide manifold opportunities to support shop floor personnel in pursuing improvement opportunities. Translating organizational priorities into goals for daily work (MB26) depicts one exemplary MB that can help enable workers to conduct improvements by focusing their efforts in productive ways. As PharmaCo C points out, providing shop floor workers with a clear direction and focus for daily work is of high importance in the pharmaceutical environment, given the perceived dichotomy between improvement (OPEX) and maintaining a state of control (compliance). Ambiguous or seemingly conflicting corporate and shop floor priorities can cause disengagement in OPEX activities. At PharmaCo C, managers are therefore informally expected to help shop floor personnel integrate OPEX into daily operations by providing clear and actionable guidance to enable and motivate them to adopt the desired SFB. By enabling shop floor personnel to act in desired ways it can make them consider OPEX as a legitimate way of working, which can in turn contribute to adoption of desired SFB.

5.2.3.3 Intended Sanction-focused Management Behaviors

Finally, *sanction*-focused MBs are identified. In contrast to *power*-focused MBs and *communication*-focused MBs, the inverse of sanctioning is not simply not sanctioning, but rewarding. As a result, we include in this category MBs that range from sanctioning to its inverse in terms of rewarding. In this context, recognition is viewed as a form of reward. The identified *sanction*-focused MBs can therefore be viewed as MBs that legitimize norms by encouraging compliance with existing ones through sanctioning or rewarding, respectively by establishing new ones. In the context of OPEX programs, these norms can have multiple facets, which include among others standard procedures, performance targets and prescribed behaviors.

The identified MBs can be clustered into four interrelated categories, which include *confirming process execution*, *recognizing achievements*, *confirming performance levels*, and *conducting performance dialogue*. They are intended to facilitate the SFBs adhering to standards, identifying improvement opportunities, identifying root causes, and acting on improvement opportunities. For this purpose, they address the behavioral mechanisms motivation, enablement, discipline, and data-orientation.

Table 34: Sanction-focused Management Behaviors

Sub-Category	Management Behavior (MB)	Intended SFB	Effect Mechanism	Addressable Unintended MC Effect (UME)
<i>Confirming Process Execution</i>	- Review standards in action (MB37) - Assess adherence of shop floor activities to confirmation criteria (MB38) - Provide constructive feedback in the process and intervene if necessary (MB39) - Assess shop floor employee conduct in the process (MB40)	Adhering to standards, Identifying improvement opportunities, acting on improvement opportunities	Discipline, enablement	- UME13 - UME05, UME13 - UME04-E05, UME13, UME18-19 - UME04, UME13, UME18-19
<i>Recognizing Achievements</i>	- Recognize adequate behavior (MB41) - Seriously consider improvement ideas (MB42) - Share and celebrate successes (MB43)	Identifying improvement opportunities, acting on improvement opportunities	Motivation	- UME01, UME13, UME18 - UME04, UME06, UME21-23 - UME13, UME21
<i>Confirming Performance Levels</i>	- Challenge current performance level beyond compliance (MB44) - Visualize performance gaps (MB45) - React to ever 'green' KPIs (MB46) - Take action, if KPIs show 'red' (MB47)	Identifying root causes, acting on improvement opportunities	Motivation, data-orientation	- UME03, UME09, UME12 - UME06, UME09, UME11-12 - UME03-04, UME09 - UME03-04, UME09
<i>Conducting Performance Dialogue</i>	- Engage in honest and open dialogue (MB48) - Create a psychological safety environment (MB49) - Initiate weighing the risks of not making a respective change (MB50)	Identifying improvement opportunities, acting on improvement opportunities	Motivation, enablement, data-orientation	- UME07, UME12 - UME12 - UME02, UME14

Effects on Intended Shop Floor Behavior

Adhering to Standards

In order to ensure that shop floor personnel adhere to standards intended MBs that relate to *confirming process execution* are identified. They are intended to ensure disciplined process execution of shop floor personnel in terms of both adherence to procedures and adequate behaviors. Among others, they therefore address worker discipline as a key behavioral mechanism.

They identified MBs further seek to assist shop floor personnel in complying with these standards. The identified MBs related to facilitating adherence to standards therefore complement the application of the MC dimensions *standardized work* and *goal setting*, by putting a strong focus on facilitation, reinforcement and improvement of existing standards. They further support goal alignment and motivation of shop floor personnel by providing workers with regular, informal and structured feedback.

Identifying Improvement Opportunities

The identified *sanction*-focused MBs can help facilitate intended SFB in terms of identifying improvement opportunities by addressing the behavioral mechanisms motivation, enablement, and data-orientation. Overall, intended MBs from three subcategories are identified, including *confirming process execution*, *recognizing achievements*, and *conducting performance dialogue*.

Intended MB for facilitating the intended SFB include recognizing adequate behavior (MB41) and providing constructive feedback in the process and intervene if necessary (MB39). Based on the former, managers can increase workers motivation that can result in higher engagement in improvement activities. Based on the latter, on the other hand, managers can help enable shop floor personnel by providing individual guidance in the process.

Acting on Improvement Opportunities

All four identified subcategories of *sanction*-focused MBs include behaviors that can encourage workers to act on improvement opportunities. Motivation, therefore, depicts a key behavioral mechanism of the *sanction*-focused MBs.

In addition to motivation, data-orientation is identified as a critical mechanism to direct shop floor personnel towards acting on improvement opportunities. Exemplary intended MBs include challenging current performance level beyond compliance (MB44) and initiate weighing the risks of not making a respective change (MB50).

Based on these behaviors, managers can create a data-driven sense of urgency. We consider these MBs as *sanction*-focused, since their primary purpose can be viewed as an intervention intended to legitimize a course of action based on explicit or implicit norms.

Identifying Root Causes

Finally, MBs within the subcategory *confirming performance levels* are identified that can facilitate identifying root causes. They can be viewed as addressing the behavioral mechanisms enablement and data-orientation. On the one hand, they facilitate feedback, which can provide workers with additional guidance. On the other hand, they focus on utilizing data to affect behavior.

In order to facilitate identification of root causes, the studied companies emphasize the importance of managers routinely engaging in validation of performance levels during daily meetings. Several interviewees emphasize a lack of data-orientation as part of daily work on the shop floor as one potential reason for lack of continuous improvement as part of their OPEX programs. Suggested MBs that can address this potential short coming include visualizing performance gaps (MB45), reacting to ever 'green' KPIs (MB46), and acting, if KPIs show 'red' (MB47). All can be viewed as starting points for further investigation into underlying root causes. As the MBs are intended to be embedded within a daily meeting routing, they are assumed to contribute to continuous improvement of SFB in terms of identifying root causes.

Addressable Unintended Management Control Effects

By addressing a variety of behavioral mechanisms, including discipline, motivation, enablement, and data-orientation, the identified *sanction*-focused behaviors can mitigate a variety of unintended MC effects. The underlying intended MBs can be viewed as covering the entire spectrum of legitimation, from reward in the form of recognition to sanction in terms of critical reflection of the status quo. To illustrate, the behaviors related to subcategory *recognizing achievements* can provide legitimation to desired SFB by establishing implicit aspirational norms. As a result, they can result in increased levels of employee motivation. In contrast, the identified MBs related to *confirming performance levels* and *conducting performance dialogue* can contribute to reconfirming performance-oriented norms, which can increase levels of discipline, or data-orientation. Finally, we identify *sanction*-focused MBs, such as those from subcategory *confirming process execution*, which can be considered neutral on the spectrum between sanctioning or rewarding. By providing constructive feedback, for

example, managers can increase levels of enablement of shop floor personnel, in terms of neutral feedback.

Conclusion

From comparing the intended MBs from all three behavioral dimensions in terms of intended effects, we find that the identified MBs can support all seven facets of intended SFB (cf. *Table 35*). At the same time, the MBs of none of the three MB dimensions support all relevant facets of intended SFB.

All three MB dimensions have in common that they bear the potential to support the two aspects of intended SFB *identifying improvement opportunities* and *acting on improvement opportunities*. All other facets of intended SFB are associated only with subsets of the three MB dimensions, or even only with one MB dimension. For example, *adhering to standards* is addressed by both *communication-focused* MBs and *sanction-focused* MBs. Similarly, *fact-based decision making* is supported only by the identified *communication-focused* MB.

Table 35: Overview of facets of SFB that are addressed by identified MB

Intended SFB	Communication-focused MB	Power-focused MB	Sanction-focused MB
<i>Identifying improvement opportunities</i>	•	•	•
<i>Identifying root causes</i>			•
<i>Timely and independent decision making</i>		•	
<i>Acting on improvement opportunities</i>	•	•	•
<i>Highlighting issues that require escalation</i>	•	•	
<i>Adhering to standards</i>	•		•
<i>Fact-based decision making</i>	•		

Like the facets of intended SFB, the identified MBs can address each of the derived unintended MC effects (cf. *Table 36*). Some of these effects can thereby only be addressed by one of the three categories (e.g. UME03), while others can be addressed by MBs from all three dimensions (e.g. UME04). Like the aspects of intended SFB, our findings further suggest that the MBs of none of the three MB dimensions can address all relevant unintended MC effects.

Table 36: Overview of unintended MC effects addressable by identified MB

Unintended MC Effect (UME)	Associated MC dimension	Communication-focused MB	Power-focused MB	Sanction-focused MB
UME01	Std	•	•	
UME02	Std	•	•	•
UME03	Std	•		
UME04	Std, Vis, GS	•	•	•
UME05	Std			•
UME06	Std			•
UME07	PM, GS		•	•
UME08	PM, GS	•	•	
UME09	PM	•	•	•
UME10	PM			
UME11	Vis	•		•
UME12	Vis			•
UME13	Vis	•	•	•
UME14	EE, Tr	•	•	•
UME15	EE	•	•	
UME16	EE	•	•	•
UME17	EE	•	•	
UME18	Tr	•	•	•
UME19	Tr	•	•	•
UME20	Tr	•	•	
UME21	Tr	•	•	
UME22	Tr, GS		•	
UME23	GS	•	•	
UME24	GS	•	•	
UME25	GS	•	•	

Finally, the findings from the qualitative analysis suggest that all identified MBs can be viewed as supportive, since each bears the potential to strengthen intended MC effects in terms of intended SFB, to address unintended MC effects, or both. Unintended effects of each of the six MC dimensions can thereby be addressed by MBs of each of the three categories. Each dimension is further viewed as relevant for impacting SFB in desired ways. On the one hand, each can address a broad scope of aspects of intended SFB and unintended effects. On the other hand, each bears the potential to impact individual aspects of SFB, respectively unintended effects exclusively.

5.2.4 Management Standard Work

“Es ist nicht genug zu wissen, man muss es auch anwenden; es ist nicht genug zu wollen, man muss es auch tun.”¹⁴

Johann Wolfgang von Goethe

The conducted desk research suggests that nine out of the ten studied companies recognize the importance of management behavior for supporting OPEX. Yet, only three companies also formalize the intended behaviors that managers should apply to support impacting SFB for OPEX in the form of MSW (cf. *Table 24*). Another two OPEX programs acknowledge the relevance of MSW as an OPEX success factor, but do not further specify what routine behaviors are adequate beyond generic OPEX related management principles such as ‘build trust’, ‘engage everyone’ or ‘manage change’. The remaining OPEX programs do not yet cover MSW at all. In the following, the MSW concepts of the three companies that have formalized supportive MB categories as part of MSW to support OPEX are outlined.

5.2.4.1 Case 1: PharmaCo A

General information:

PharmaCo A is one of the largest manufacturers of patented drug products globally. It counts more than 50.000 employees and it operates more than 20 manufacturing sites across Europe, the U.S. and Asia. The product portfolio includes drug substances as well as sterile and non-sterile drug products.

In the past, the company produced many high-volume products, like many of its competitors. Today, there is a trend towards more personalized healthcare the company is pursuing. In order to be able to respond to the new customer demands while keeping cost at the right size, the company is shifting production towards more high potency products, smaller lots, higher numbers of change overs, more flexible plants, and single use technology. Sustained productivity and agility therefore comprise its two key strategic priorities.

The organization has the ambitious goal of increasing the number of products produced by three to five times, while halving the cost for society. In order to meet the

¹⁴ Translated from German: «Knowing is not enough; we must apply. Willing is not enough; we must do.»

projected demand for the company's products, its OPEX program needs to enable the organization to work faster along the regulatory processes to shorten the timeline for the value creation process, while keeping quality levels high.

The company employs OPEX professionals on both a local and on a global level. On the global level, OPEX professionals work within global business functions, which is the company's global support function organization. They can be considered the architects of the company's OPEX program. OPEX professionals on the local level are part of global operations, which is the company's global manufacturing network.

One of the key challenges that PharmaCo A is currently tackling is enabling OPEX professionals in terms of capability building to actively support OPEX implementation. Specifically, the company is facing the challenge of defining and then building the right capabilities that enable OPEX leaders for this task. In the past, the company had a lot of employees that went through different belt trainings, but that did not transform knowledge into capabilities by becoming active practitioners after completing the trainings. Instead, trainings often resembled one-time efforts that primarily helped professionals to boost their curriculum.

Another connected challenge is the difficulty to make leaders fully understand and embrace their role for OPEX. While OPEX literature emphasizes that OPEX is a leader led concept, the company is struggling to operationalize the full implementation of it. In particular, the company has difficulties to get managers to fully internalize and demonstrate adequate conduct in terms of routine MB for OPEX. While the company has seen some good examples on the individual level, a broad and systematic implementation still represents a major challenge that the company has not yet overcome.

Corporate OPEX approach:

The company launched its OPEX program in 2016. Prior to that, both legacy and newly acquired organizations have been doing Six Sigma with a strong focus on getting employees certified in Six Sigma. While legacy initiatives were also referred to as OPEX in the past, the previous improvement program had almost exclusively elements of Six Sigma. Other common OPEX elements were not in the focus before the launch of its recent program in 2016.

PharmaCo A combines elements of a centralized and a decentralized OPEX approach. The OPEX organization is comprised of so called OPEX leads from a central technical operations OPEX organization as well as from manufacturing units in global functions that oversee the drug substance, and the drug product sites. During the launch

of the OPEX program, each of the manufacturing units in global functions was asked to identify lead areas where they could pilot the OPEX program by applying some of the components where it makes sense as a way of getting familiar with it. Those lead areas then learned by doing at the site level, which is where the decentralized parts come in. However, decentralized doesn't mean that everybody does what they want, rather that they are taking the corporate OPEX framework and applying it based on local business problems.

Management Standard Work Components

MSW at PharmaCo A seeks to enable managers to grow a culture of quality, continuous improvement, and inclusion, which are all considered critical for OPEX in pharmaceutical manufacturing. To help managers systematically guide organizational in a way that is aligned with this goal, MSW formalizes two interconnected components. On the one hand, it defines key opportunities for interacting with shop floor personnel in order to guide SFB in desired ways. We refer to these in the following as standard management interactions, which comprise in the case of PharmaCo A *coaching* and *problems solving*. On the other hand, it formalizes standard MBs, which define specific behaviors that managers should follow. They are designed to guide management conduct in a way that facilitates the effective execution of the standard management interactions in terms of engaging shop floor personnel to adopt desired behaviors. These standard MBs comprise the five categories *focus*, *take ownership*, *see and understand firsthand*, *continuously improve*, and *bias to action*.

The behaviors underlying the five standard MB categories were obtained by consolidating internal lists of organizational behaviors, which are considered successful for OPEX. Overall, the company involved a diverse group of 40 individuals from the global technical operations division in the process of deriving adequate behaviors, including local and global OPEX managers, site leaders, lab technicians and operators.

The first standard MB category *focus* requires managers to periodically orient organizational efforts towards activities that are aligned with OPEX objectives. Managers should continuously help shop floor personnel understand the link between their daily tasks and broader organizational goals and direct their attention accordingly. To achieve this, managers should continuously and consistently explain to shop floor personnel the rationale behind different aspects of OPEX and relate them to organizational priorities. They should further routinely simplify and prioritize organizational efforts in alignment with business goals.

The second category *take ownership* aims at facilitating shop floor personnel commitment to OPEX in order to ensure alignment between SFB and the OPEX program that is sustainable. To get such commitment, managers have the task to continuously encourage shop floor personnel to take ownership for improvement of the processes that they work on. Particularly, managers should routinely equip shop floor personnel with decision making capabilities and should further frequently acknowledge them for bringing in their own constructive views. In addition, managers are expected to always show trust in the judgement and expertise of shop floor personnel, when they raise issues or propose solutions to problems. Finally, managers should routinely embrace opportunities to learn from others as well as from mistakes as they happen.

The third category *see and understand firsthand* seeks to ensure that managers have a clear understanding of the current situation on the shop floor, which helps support the first category *focus*. Likewise, it should enable shop floor personnel to develop a good understanding of how their own actions related to broader organizational goals related to OPEX. To achieve both, *see and understand firsthand* requires managers to routinely visit the shop floor where the value creating work happens and to spend a significant amount of time there. By requiring managers to do this on a regular basis, the company hopes to ensure that managers do not only do so in case issues arise. To ensure managers develop a good understanding of the situation on the shop floor, they are further expected to actively listen and to encourage diverse views during shop floor visits by making sure that the voices of all shop floor personnel are heard. Related to active listening, managers should routinely step into dialogue with shop floor personnel to stimulate critical thinking and encourage active participation in OPEX activities. In terms of making sure that shop floor personnel have a good understanding of how their actions related to overall OPEX success, managers should not only to be more present on the shop floor but should also be supportive in terms of playing back valuable information to shop floor personnel. As part of this, managers are expected to regularly create opportunities for interaction with shop floor personnel to align on OPEX related topics and to practice adequate behaviors. Finally, managers as well as shop floor personnel are expected to use data and to actively engage with peers within and across functions to understand the real situation on the shop floor as it relates to broader organizational topics.

Fourth, *continuously improve* aims at instilling an improvement mindset on the shop floor that facilitates continuously generation of improvement ideas. To achieve this goal, it is provided that managers follow four more general routine behaviors aimed at facilitating improvements. First, managers should periodically make sure that standards

are adhered to in order to ensure compliance with regulatory requirements. Managers should, second, continuously challenge the status quo to bring forth new ideas to identify and eliminate waste. Third, managers are asked to regularly celebrate successes and systematically reward adequate behaviors through their own behaviors. Since the ways in which certain behaviors are recognized are in the hands of individual managers at PharmaCo A, they play a key role for recognition and encouragement of desired SFB. Finally, managers should relentlessly embrace opportunities to learn and develop new skills. In this context, managers are encouraged to embrace experimentation in order to facilitate the broader OPEX principle of incremental improvement, which relies on the ability to try many small changes in order to advance the status quo. In this context, the company promotes learning from failures in order to establish a work environment that encourages a culture of inclusion.

The fifth category *bias to action* aims at enabling SFB that facilitates quick decision making, goal orientation and problem solving based on cross-functional collaboration and teamwork. Notable MBs formalized as part of this category include leading by example, embracing constructive conflict and anticipating and removing roadblocks for shop floor personnel to facilitate goal achievement. In addition, *bias to action* requires managers to foster cross-functional work, to follow through on OPEX commitments, to act on existing issues by solving problems or, if needed, by ensuring they get escalated properly.

Embedment of MSW within the OPEX Program

The company's OPEX program is comprised of eight core components, which cover overall more than 30 operations-oriented and people-oriented OPEX program elements. In a recent iteration of its OPEX approach the company developed an operating model for managing OPEX as a subset of the OPEX program to address shortcomings of the OPEX program with regards to engaging employee in OPEX. After launching the OPEX program in 2016, the company noticed that shop floor personnel were overwhelmed by the complexity of the OPEX program, which manifested itself in a lack of adoption of the various OPEX program elements for improvement of daily work. The lack of employee engagement was viewed because of the lack of guidance the OPEX program provides on how the people-oriented elements relate to each other. Introducing the OPEX program in all its complexity to the employees without providing practical guidance was described by one interviewee as "dropping the house on people", which is a reference to the TPS house (cf. chapter 2.1) with which the full OPEX program has

some resemblance. To overcome this issue, the additional operating model now provides actionable guidance for managing OPEX by setting the focus on the people-oriented OPEX sub-system and relating the relevant elements to each other.

The operating model comprises six elements that describe how relevant people-oriented components can play into each other by bundling them in a sequential model (cf. *Figure 22*). At the center of the operating model is MB, which depicts the underpinning of all other element of the people-oriented sub-system. The second element of the management model is strategy deployment covering both *goal setting* and cascading of goals throughout all levels of the organization. Providing a clearly defined focus of what needs to be worked on is viewed as key prerequisites for guiding SFB effectively. Strategy deployment is therefore intended to help translate the company's strategy into goals, KPIs and ultimately into organizational actions. The third element, daily performance management covers, among others, aspects of *performance measurement* and *visualization*. It involves regular meetings at performance boards that help to make the current performance levels visible to identify variance from targets based on visual metrics. Possible root causes for variance from targets that PharmaCo A looks for include deviations from process standards or a lack of existing standards to start with. The fourth element relates to *standardized work*. It is used to define a baseline in terms of how work should be done and furthermore to help determine deviations from standards. In case of deviations from standards, the standard management interactions *problem solving* is initiated to facilitate CI, which represents the fifth model element. It is followed by the second standard interaction, which represents the final element of PharmaCo A's operating model.

Both MSW components, standard management interactions and standard MBs, are embedded as separate elements within the operating model. The standard management interactions *problem solving* and *coaching* represent two of the five model phases that should be continuously run to ensure sustainable OPEX implementation. The standard MB, in contrast, are intended to help guide SFB in desired ways along the phases of the operating model to facilitate the effective continuous execution of the model loop. Both are therefore recognized as key levers for engaging shop floor personnel by enabling them to participate in the continuous process of identifying and closing performance gaps.



Figure 22: Embedding of MSW in PharmaCo A's OPEX Program

The main role of the standard MBs is to equip managers for their role as OPEX leaders along all phases of the model loop. Fundamentally, change in organizational behavior as required as part of OPEX implementation is considered the outcome of the actions of all organizational members. Changing behaviors is therefore believed to require extensive commitment, time and practice. To ensure organizational commitment and practice, the company places a strong emphasis on how managers conduct themselves daily, since their behavior is expected to set the tone for the rest of the organization. One main purpose of the standard MBs is therefore to facilitate adequate and continuous management commitment by providing managers with behaviors to replicate daily. They are further defined with the focus on facilitating adequate behavior and fruitful exchanges and conversations during shop floor visits. Among others, managers are expected to continuously remove roadblock for shop floor employees, who are in turn expected to solve any operations related issues that may occur. To facilitate this, managers are expected to frequently go to the shop floor to understand the situation at the place of value creation. The company has further identified going to the shop floor with the right intent and attitude as another success factor, since visits by managers can cause disruption in case employees feel being spied upon or have the view that managers are not there to truly help or understand. This contrasts with the management approach that the company applied in the past, which aimed to ensure management commitment and presence at the shop floor based on an approach it referred to as 'managing by walking around'.

Finally, *coaching* and *problem solving* are organizationally embedded involving multiple organizational levels to facilitate sustained organizational improvement. The scope of the respective standard management interactions varies based on organizational

role and proficiency levels of the respective individual. In this context, the company distinguishes between the three categories or organizational roles namely problem solver, coach and coach of coach. While shop floor personnel are mainly limited to the role problem solver, since they are primarily expected to solve all operational issues as outlined above, managers can adopt all three roles as part of standard management interactions. With regards to *problem solving*, standard management interactions include active participation in *problem solving* as well as providing dedicated *coaching* specifically during the process of solving an identified issue, either as coaches or as coaches of coaches. The standard management interactions *coaching* on the other hand comprises continuous development of *coaching* internal resources, personal development and identifying *coaching* opportunities.

5.2.4.2 Case 2: PharmaCo C

General information:

PharmaCo C is a leading manufacturer of patented pharmaceutical drug products. It employs more than 50.000 employees. It operates more than 50 production sites with plant typically being of a size between 50 and 3.000 employees. The company produces both chemical and biological drug substances, as well as both sterile and non-sterile drug products.

The company started its OPEX journey in 2004 with an initial focus on quality improvements as part of Six Sigma initiatives. The focus of these initiatives was on process robustness to increase the effectiveness of operations by preventing losses from process instabilities. After this initial quality focus, the company has shifted its focus to increasingly incorporate efficiency perspectives on operational improvements in order to achieve balanced and best-in class operational performance levels. Its current strategic objective is to define one best way of working through the entire operations of supply and manufacturing. The overarching goal of this one best way of operating is to increase the operational performance levels in delivering pharmaceutical products in a way that benefit the patients by unleashing the potential of the employees in global operations.

The OPEX program of PharmaCo C is centrally governed and supported. The central OPEX organization governs among others pre-assessment, preparation as well as program deployment at a plant. The OPEX program that is rolled out is identical for all plants of the organization. What can vary based on plant maturity is the focus of capability building that follows a predefined sequence.

As two key challenge for engaging the workforce in OPEX, the company identified resistance to change and a lack of OPEX knowledge and capabilities. In addition, it highlights limited resources as a challenge, since all corporate improvement initiatives have a maximum return on investment of two years.

Management Standard Work Components

PharmaCo C applies MSW to facilitate a management-led transformation of daily work as well as change of the organizational culture that increases the effectiveness of process execution by shop floor personnel. The company's perspective is that SFB follows the behavior of managers. MSW, therefore, involves a wide range of management roles, including site leads, functional leads, operating units leads, OPEX facilitators, or strategic specialists.

The company's MSW concept covers three categories of routine activities that managers should follow to successfully guide SFB. These include *coaching*, *confirmation of key processes* and *confirmation of key outputs*. All three are intended to be performed during regular shop floor visits by managers. While the MSW concept defines critical management activities, the company has not yet fully formalized set of MBs that support impacting SFB in desired ways. Accordingly, it does not provide managers with recommended behaviors that they should adopt to support the execution of said MSW activities. In the following, we therefore focus on the MBs that the interviewed experts expect to support the MSW activities.

The first category *coaching* is designed to help shop floor personnel engage in OPEX through supervised and experiential learning. The company's expectation is that shop floor personnel increasingly drive CI from the bottom-up, without heavy reliance on middle or upper management. To meaningfully contribute to CI, they need to be capable, among others, to identify, select and solve relevant issues. *Coaching* shop floor personnel how to fulfill these tasks successfully is therefore viewed as a key mechanism for engaging shop floor personnel in OPEX. To fulfill this critical task, the company distinguishes two types of *coaching* as part of MSW, which are applied based on both site maturity and business need and in a predefined sequence, as outlined below. Both types are further intended to supplement theoretical OPEX trainings.

As part of the first type of *coaching*, managers are expected to routinely provide practical guidance in the process by actively stepping in during process execution to correct counterproductive behaviors. It is described similarly to the way a driving instructor would intervene in critical situations. As part of this first part of *coaching*,

managers are therefore expected to promote and constrain desired respectively undesired SFB.

The second type of *coaching* requires managers to help shop floor personnel to notice counterproductive behaviors themselves, which initially may not be visible to them. Possible reasons for such a lack of awareness include, among others, being accustomed to certain ways of work or lack of OPEX capabilities. In order to fulfill this task, managers are expected to routinely observe shop floor activities as they happen. They further need to help shop floor workers unlock their full potential in terms of OPEX, for which managers are expected to adopt the role of both a motivator and a promoter of the company's OPEX program.

The second MSW category *confirmation of key processes* requires managers to routinely evaluate the processes for which they are accountable for in two ways. First, they should routinely check, if these processes are working robustly. Second, and more specifically, they should check if shop floor personnel follow existing standards. The manager's task for the former in the context of impacting SFB is to routinely check if all relevant process standards exist and are further rolled out for the respective process. In case standards are not available, as the accountable individual for the respective process, the manager should address the issue in a timely manner. For the latter, in terms of adherence to standards, managers are expected to regularly confirm if standards are being followed by shop floor workers. In case of deviations, they should highlight it to the involved shop floor personnel, without any judgement or blame.

Similarly, the third category *confirmation of key outputs* requires managers to routinely ensure that processes for which they are accountable for deliver the required outputs. In contrast to *confirmation of key processes*, which focuses on the ways in which processes are executed, *confirmation of key outputs* requires managers at PharmaCo C to critically evaluate if organizational efforts are focused on the right things. In the past, the company observed an overemphasis on methodology in terms of doing things right, to the neglect of proper opportunity selection in terms of doing the right things. This has led, however, to situations where many improvement projects were launched primarily for the sake of completing projects without focusing on selecting issues that are worth addressing. Identifying the right problem to solve is now considered the first necessary step, whereas implementing new methods or processes is viewed as only the second necessary step, which is dependent on the issue at hand. The company has therefore recently moved from a static activity-based maturity review to a more performance-based review. Opportunity selection has since become increasingly important, which is seen as a big change in goal setting for the company's OPEX

program. Creating transparency on current levels of performance and identifying deviations from planned goals is therefore seen as a key management activity for impacting SFB in desired ways. As part of *confirmation of key outputs*, managers should further routinely ask shop floor personnel for performance data that allows identifying issues as critical areas of losses. Finally, they should encourage shop floor personnel to focus on data-based opportunity selection by routinely confirming performance levels towards set goals.

Embedment of MSW within the OPEX Program

PharmaCo C's OPEX program is designed to deliver business value by providing one best way of working that helps to improve operational performance in a structured and predictable way. It comprises three separate systems, the *operating system*, the *people & cultural system*, and the *leadership system*. The *operating system* is comprised of common OPEX program elements covering, among others, elements related to MC as well as operations-oriented OPEX practices. The *people & cultural system* covers different corporate initiatives directed at building a common set of values and a quality-oriented organizational culture. Finally, the *leadership system* covers aspects of MC as well as different types of management tasks. In conjunction, the three systems guide the implementation of OPEX at the company, spanning in total seven organizational levels from shop floor level to top management level.

MSW is embedded within so-called leadership cycles of which the *leadership system* is comprised of. The leadership cycles are structured along the PDCA cycle (cf. chapter 2.1.), covering the three phases *plan*, *run*, and *improve*. The MSW components outlined above are anchored within the phases *improve*. In addition to the routine activities defined as part of MSW, the leadership cycle further includes several routine tasks as part of the *plan* phase, including *definition of purpose and roles*, *definition of goals & targets*, *preparation of visual management & meeting cascade*, *preparation of CI process*, as well as *preparation of structured gemba*. In contrast to the MSW components, these tasks can be viewed as representing desk work, rather than interactions with shop floor personnel. Finally, the subsequent *run* phase covers the task *execution of visual management & meeting cascade*, which is performed by all organizational members involved in the respective functional area.

Leadership cycles exist on different organizational levels at PharmaCo C. They interact with each other through bidirectional information flow (cf. *Figure 23*). In one direction, performance information and requests for support from regular management

reviews are reported respectively escalated across from shop floor level to top management level. In the opposite direction, planned goals and targets are cascaded down across the same organizational levels. The leadership cycles therefore represent a key mechanism for *goal setting* across all organizational levels.

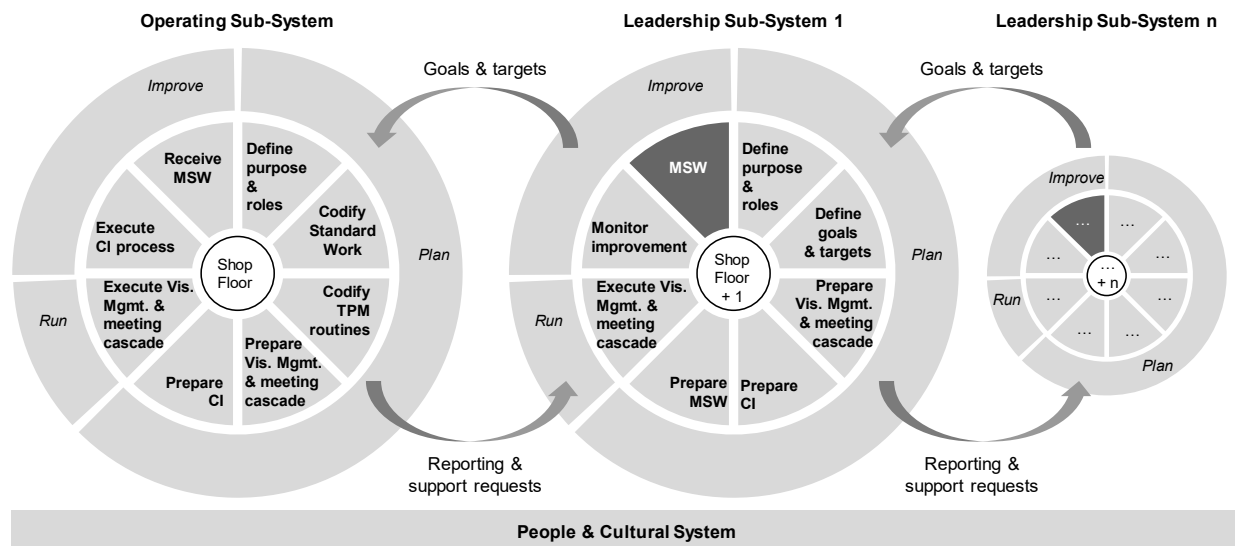


Figure 23: Embedding of MSW in PharmaCo F's OPEX Program

Finally, while the *leadership system* and the *operating system* share common OPEX program elements and are directly interconnected through the bidirectional information flow as outlined above, the *people & cultural system* comprises values, behaviors and initiatives that are not specific to OPEX programs but are related to the broader field of organizational change. Examples include values such as 'inclusivity', behaviors such as 'striving to benefit patients' or initiatives such as regular workshops, surveys and trainings related to embracing and adopting organizational change.

5.2.4.3 Case 3: PharmaCo F

General information:

PharmaCo F has a network of more than 25 internal sites and a broad network of external CMO supply sites. The manufacturing network is divided into three operating units and three regions, so it's somewhat of a hybrid network of sites aligned to either an operating unit or one of the three regions. The operating units are defined based on commonality of focus in terms of type of drugs, such as biologics drugs, or small molecule drugs. Beyond that, sites can also be split by regions based on their geographic focus in terms

of supplying products to certain regions or to a particular locally operating internal site. Hence, the hybrid approach of 3 operating units and 3 regions across the globe.

The company considers high efforts for making changes to GMP systems or agency filings as well as the company's ability to even implement changes as key challenges for OPEX. Another challenge concerns the adoption of OPEX practices and getting the different leadership layers on board with OPEX approaches, and with leading the way in that regard. Especially in the very large organization that PharmaCo F has become with more than 50.000 employees, the interviewee sees lack of effective communication as a key challenge. So, just the cascade of information and having all leadership aligned on the same page and supporting the OPEX program and its implementation has become a big challenge. To illustrate, communicate effectively, influence leaders effectively, have leadership understand and support the approaches, having leadership talk the same language with their teams, those are all challenges that the interviewee knows from working in PharmaCo F.

Corporate OPEX approach:

The legacy company started its OPEX journey formally in 2014, whereas the acquired company started its OPEX journey almost 12 years ago. The most recent program is now a little over a year old. However, it is not a completely new program. As the company puts it, it brought together the best from both legacy companies to bring it together in the new program. Hence, there are some OPEX program aspects that are new to each legacy company.

The current OPEX program is housed within a broader program that depicts the company's operating system. The operating system comprises best-known methods for various areas, including the OPEX work stream, in addition to five other work streams. These include work streams focused on quality control labs, end-to-end supply chain, people, culture and change, site and network development, as well as digital innovation.

OPEX organization sits within the strategy and business excellence function of PharmaCo F, which is a strategic central group within global manufacturing and supply organization. It is, therefore, primarily focused on global manufacturing and supply. However, the OPEX Program Office also partners closely with global quality, which can be viewed as a sister organization. The focus of the OPEX program is network wide and includes both internal and external CMO manufacturing sites. It further includes both drug substance and drug product manufacturing.

Management Standard Work Components

The company considers MSW the primary lever for guiding SFB for OPEX. PharmaCo F views shop floor personnel that solves occurring problems on their own as the target state. The main goal of MSW is therefore to help managers engage shop floor employees in the process of CI. To assist managers in this regard, the company has defined five critical MSW components for impacting SFB, namely *gemba walks*, *coaching*, *process confirmation*, *visible calendar and guidelines* as well as *being coached*.

The first component, *gemba walks*, requires managers to conduct regular shop floor visits by defining among others the expected visit cadence. The company experienced that when managers are not up to date with the operational challenges on the shop floor, they have difficulties to set adequate goals and priorities that facilitate OPEX. Hence, they should visit the shop floor regularly to get an on-site impression of existing problems as well as of the day-to-day operations as they happen. Being at the shop floor further represents a prerequisite for interaction with personnel on the shop floor and therefore for impacting SFB. The company considers presence on the shop floor critical for two main reasons. First, it enables managers to exert influence on SFB in ways that is in line with OPEX objectives, by creating regular opportunities that bring them into dialogue with each other. Second, it enables them to learn directly from shop floor personnel about potential challenges for pursuing OPEX, which in turn enables them to mitigate potential roadblocks OPEX. Engaging in a dialogue and learning on-site are, therefore, at the core for impacting SFB with *gemba walks* at PharmaCo F.

The second MSW component, *coaching*, is aimed at equipping shop floor employees with the capabilities necessary to solve problems on their own. The expectation for shop floor personnel is that they identify and highlight issues and opportunities for improvement and further work on improvements as part of their daily work. Managers are specifically not expected to solve occurring problems on the shop floor. The broader goal of *coaching* is therefore to turn shop floor employees into active participants in the process of CI rather than making them passive followers. *Coaching*, therefore, goes beyond what the company refers to as simple training, which is primarily focused on conveying knowledge. In contrast to that, *coaching* focuses on more holistic capability building to enable shop floor employees to solve problems independently. This does not only require managers to train shop floor employees, but also to help them practice the intended behavior in a controlled environment that allows employees to get comfortable with applying intended methodologies. Accordingly, the MSW component *coaching* is intended to help transform desired behaviors into habits and eventually into capabilities for solving problems that may occur.

Third, the company has defined *process confirmation* as a MSW component to ensure that relevant processes for OPEX are following standard procedures. It concerns the work that is being done at all shop floor team levels and it is part of the work that's being done by managers when they go visit the shop floor. The company expects managers to periodically check the degree to which shop floor employees organize, maintain and continuously improve their workplace in alignment with the overall OPEX program. In this context, managers are instructed to evaluate the situation on the shop floor as part of *process confirmation* along the following questions:

- *Are processes operating the way they should?*
- *If not, what observations can be made?*
- *If not, are improvements to the standard necessary?*
- *If not, how can the processes be brought back to the standard or the best-known way?*

Process Confirmation is viewed as the best-known way to ensure that employee engagement in OPEX can thrive, without negating the need for management oversight in the regulated environment. While controlling the employees' adherence to standards on the one hand and striving for maximum employee engagement on the other hand can be viewed as a dichotomy, the company considers both essential for OPEX in a regulated industry, such as pharmaceutical manufacturing.

Much like *coaching*, also *process confirmation* is tied to *gemba walks* in that being on the shop floor can be viewed as a prerequisite for providing *coaching* in the process and for *process confirmation*. Despite this fact, the company depicts them as three separate components of its OPEX program. For PharmaCo F, *process confirmation* represents an effective way to support both. On the one hand, observations made as part of *process confirmation* depict opportunities for managers to engage in further *coaching*. On the other hand, it gives managers a reason to visit the shop floor with a purpose, which can ultimately help them get a better understanding of the processes that they are accountable for.

Fourth, the MSW component *visible calendar and guidelines* fulfills two separate purposes within PharmaCo F's OPEX program. On the one hand, it seeks to ensure that managers follow standard procedures, similarly to how shop floor employees are expected to follow SOPs. For this purpose, the manager's adherence to MSW is tracked analogously to the way that production processes are regularly checked as part of *process confirmation*. Intended effects of *visible calendar and guidelines* include increased manager engagement in OPEX and increased sustainability of MBs. On the

other hand, it seeks to provide better transparency on management accountability, both for the managers and for shop floor employees, which can increase the visibility of management commitment.

Finally, the company defined *being coached* as the fifth critical MSW component. *being coached* is aimed at helping managers routinely enhance their understanding of OPEX, in order to better engage shop floor employees in the process of CI by building capabilities. To help managers to fulfill this role, managers are expected to be coached on a regular basis by other OPEX professionals from the site or from the central OPEX organization.

Embedment of MSW within the OPEX Program

PharmaCo F has placed MSW at the center of its OPEX program, due to the central role it assumes according to the company for engaging employees in OPEX. MSW represents one of twelve core elements of the OPEX program (cf. *Figure 24*), which is connected to all other core elements. The connecting layer between MSW and all other OPEX program components is represented by employee engagement, given its potential to affect OPEX implementation by impacting organizational behavior. Finally, the remaining components orbit MSW, representing equally important operations-oriented as well as people-oriented elements of PharmaCo F's OPEX program.

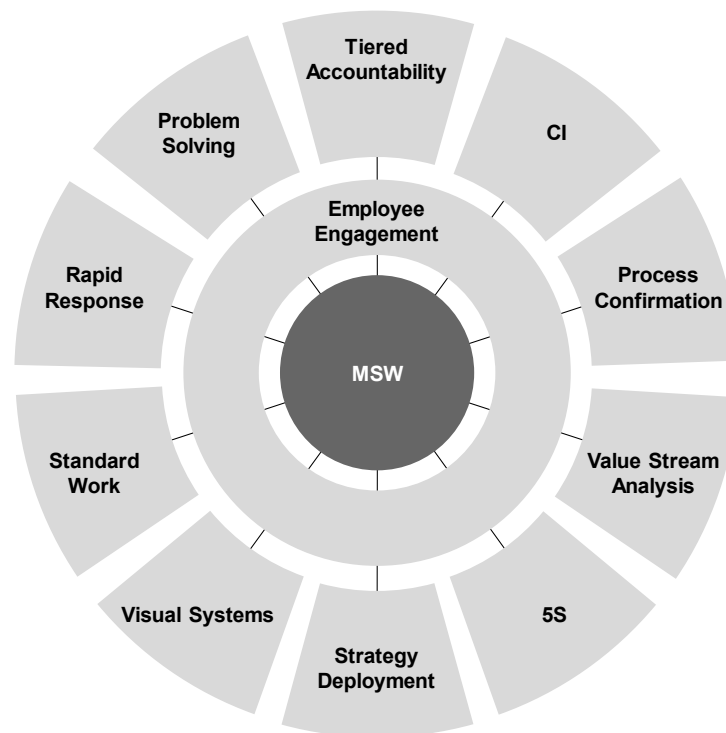


Figure 24: Embedding of MSW in PharmaCo F's OPEX Program

According to PharmaCo F, MSW can help engage employees in OPEX by addressing issues of organizational change, capability building and management support. Issues that the company has experienced in this context include, among others, micromanagement by supervisors, lack of management commitment for OPEX, lack of performance orientation, lack of OPEX capabilities on the shop floor, and more broadly lack of CI.

In order to impact SFB, the company further sees a lot of potential in integrating MSW with specific components of its OPEX program. Particularly, it identifies the integration of its MSW concept with *strategy deployment*, *visual systems* and *tiered accountability* as an effective management approach for successfully impacting SFB both in the near-term and in the long-term. *Strategy deployment* and *visual systems* closely relate to our MC dimensions *goal setting* and *visualization*. *Tiered accountability*, on the other hand, is a term for which there are varying concepts in different organizations. At PharmaCo F, *tiered accountability* establishes a process for cascading expectations, goals, support requests or performance information across different organizational levels. Among others, it specifies among other roles and responsibilities, KPIs as well as the cadence for shop floor meetings.

First, *strategy deployment* and MSW are considered supplementary for impacting SFB, in that the former helps set the direction for OPEX efforts throughout the organization, whereas the latter provides managers with routines for ensuring shop floor personnel follow the intended direction. Components of MSW that are critical for PharmaCo F in this context comprise *process confirmation* and *gemba walks* and *coaching*. *Process confirmation* and *gemba walks* can help provide shop floor personnel with regular feedback from manager related to the degree to which current performance levels meet expectations based on set goals. In combination with *strategy deployment*, they help address the lack of performance orientation on the shop floor. *Coaching*, on the other hand, is considered supportive in terms of enhancing the ability of everyone to engage in CI in order to help achieve set goal, thereby directly addressing the issue of lack of OPEX capabilities. In this context, the company emphasizes the importance of supplementing generic *training* programs with regular *coaching* on the shop floor. On the one hand, pharmaceutical operations are often considered to be knowledge intense, requiring regular *coaching* support in order to avoid overburdening shop floor personnel with OPEX. On the other hand, the company found that solving problems on the shop floor often requires alignment with cross-functions, which requires involved personnel to obtain a certain set a capability.

Next, on the one hand, *visual systems* can be complemented by *gemba walks*. To illustrate, regular interactions between managers and shop floor personnel as part of *gemba walks* at visual performance boards could support *visualization* in two ways. First, it could enhance the adoption of *visual systems*, such as visual performance boards, by shop floor personnel by demonstrating management commitment and providing support. This can in turn lead to increased levels of transparency on critical aspects of operations such as operational performance, incidents or deviations from targets. *Visual systems* can also support *coaching*. It can provide meaningful insights during shop floor visits, which can help identify deviations from planned targets or from defined standards. These can in turn be used for providing *coaching* on identification of improvement potential as well as on problem solving, which can help engage shop floor personnel in the process of CI.

Finally, MSW and *tiered accountability* are highly interconnected within PharmaCo F's OPEX program. Highly simplified, MSW defines both what managers should and how they should do it in order to support OPEX. *Tiered accountability* on the other hand provides an organizational structure that regulates who should be involved as well as when certain activities should be initiated. For example, it can specify role-based tasks for the MSW components *gemba walks*, *coaching*, or *process confirmation*. It also has the potential to put them in context with OPEX program elements that go beyond the two elements *visual systems* and *strategy deployment* as outlined above. By combining MSW with *tiered accountability*, the company sees the potential to provide leadership on different levels of the organization with clear roles, which in turn can help pull in multiple levels of the organization for OPEX. PharmaCo F further sees potential benefits in establishing comprehensively links between all OPEX program elements, including *strategy deployment*, *process confirmation*, *problem solving*, *CI*, and going as far as *employee engagement*. However, to date, while putting a strong focus on coherence of the modeling of the OPEX program, it does not a fully operational model that integrated all depicted elements into a process model. Instead, the company primarily on depicting core elements, whereas the difficult task of adopting the different OPEX program elements in an adequate manner is still mainly left to interpretation of the respective adopter.

5.2.4.4 Cross-Case Comparison

MSW plays a central role in the OPEX programs of all three studied cases. However, the conceptualization of MSW and particularly the extent to which they formalize standard MBs varies notably between the three cases. In the following, we present

comparison of the three MSW to impacting SFB with regards to integration of MSW, MB and MC.

The interviewees of all three companies formulate concrete expectations for manager conduct. Yet, PharmaCo A represents the only case, that guides MB explicitly by formalizing standard MBs for managers to replicate. In contrast, MSW of the other two companies defines intended MBs only implicitly. Instead, they formalize specific opportunities for managers to engage with shop floor personnel based on what we refer to as standard management interactions. Adopting such a task-oriented perspective enables the embedding of MSW within the broader OPEX program, in addition to guiding MB implicitly. Specifically, we observe based on the real-world examples, that these task-oriented approaches can be enriched in a practical manner with additional information to enhance the execution of these tasks. Examples include cadence, roles and responsibilities or focus topics of respective tasks. Accordingly, we consider both standard management interactions and standard MBs two components of MSW that can supplement each other. Further, the three approaches suggest that they should be integrated to provide managers with comprehensive guidance on how to conduct themselves.

An analysis on the level of the categories of intended MBs shows that the MBs implicitly or explicitly demanded by MSW of the studied cases cover all three dimensions *communication*, *power* and *sanction*, with an overweight on MBs related to *power* (cf. Table 37). For example, PharmaCo A's explicitly demanded *focus* standard MBs are closely related to the intended and *communication*-focused behaviors MB01 and MB03 from category *strategy deployment*. On the other hand, PharmaCo C's standard management interaction *process confirmation* implicitly expects MBs that are related to the intended MBs from category *role modeling* (MB05-MB07)¹⁵.

The comparison on category level further shows that *conducting performance dialogues* represents the only category that is not addressed by any of the three programs. In contrast, all three companies, implicitly or explicitly, address MBs from the categories *assigning accountability* (MB18) and *building capability* (MB22-MB24) by requiring regular shop floor visits or *coaching*. Overall, the initial comparison on category level shows a mixed picture regarding the coverage of intended MB categories by the existing MSW approaches.

¹⁵ Cf. Appendix F for an overview of the matching between intended MB categories and MSW of the case companies

Table 37: Formalization of Supportive Management Behaviors as part of MSW

	Categories of Intended Management Behaviors	PharmaCo A	PharmaCo C	PharmaCo F
<i>Communication</i>	Cascading Strategy	●		
	Role Modelling	●	○	○
	Uncovering Guidelines			○
	Instilling Improvement Mindset	●	○	
<i>Power</i>	Assigning Accountability	●	○	○
	Building Capability	●	○	○
	Simplifying	●		○
	Addressing Problems	●		
	Resolving ambiguities	●		
<i>Sanction</i>	Confirming Process Execution		○	○
	Recognizing Achievements	●		
	Confirming Performance Levels		○	
	Conducting Performance Dialogue			

- Explicitly addressed (formalized standard management behaviors)
- Implicitly addressed (formalized standard management interactions)

Based on the mapping of the three MSW approaches to addressed intended MBs, we can link MSW of the three cases to addressable UMEs (cf. chapter 5.2.3). An analysis of the UMEs that are addressable by the intended MBs formalized by MSW suggests that they can theoretically influence all 25 UMEs to some extent. They will therefore play some role in mitigating the identified categories of UMEs. A subsequent more detailed analysis of the unintended behaviors that underlying the UMEs further indicates that only around half of these are formally addressed by the existing MSW approaches. Table 39 provides an overview of the unintended behaviors that are addressable by existing MSW. In this context, we distinguish unintended behaviors on the one hand into SFB and MB, and on the other hand into the categories *communication*, *power* and *sanction*.

The analysis of unintended behaviors that are focused on *communication* suggests, among others, that issues related to the utilization of visual systems in the regulatory environment (UB12 & UB13) are not addressed by existing MSW. In a broader sense, these issues are based on a lack of clear communication that could be systematically addressed by MSW. Other unintended behaviors that could likewise be addressed with

adequate *communication*-focused MSW include *setting unrealistic goals* (UB37), which can distract SFB or *rejecting relevant KPIs as inapplicable* (UB38). Similarly, *not expressing concerns* (UB38) could be mitigated, if management can succeed in communicating concerns, including those that relate to implementing OPEX, are seriously considered by management.

With regards to the twelve *power*-focused unintended behaviors, we find that only *undercoaching* and *working in silos* are formally addressed by the studied MSW approaches. The former affects shop floor workers ability to make OPEX related decisions. It can be directly mitigated by the identified MBs from category *capability building* (MB22-MB24). *Working in silos*, on the other hand, limits the flow of relevant information that can hinder shop floor personnel to contribute to organizational success. It can be addressed in parts by the MB *anticipate and remove roadblocks and simplify daily work* (MB27). However, the effectiveness of MB27 for mitigating *working in silos* is limited by the comprehensiveness of the efforts. While MB27 is supportive for mitigating *working in silos* in principle, it may lack tangibility for eliminating it. Third, *distrusting leadership of OPEX program* (UB20) can lead to disturbed power-relations by affecting the information flow from shop floor level to upper management levels. It can potentially be addressed by *act as a coach rather than a supervisor* (MB22). In our research context distrust from shop floor personnel is expected to stem among others from a perceived lack of accounting for the complex demands placed on shop floor personnel during the pursuit of OPEX (cf. chapter 5.2.1). Providing regular *coaching* support can help mitigate such a perception by demonstrating OPEX competencies and by showing credibly the commitment of managers to support and coach shop floor personnel. The remaining unintended power-focused behaviors are not addressed.

Finally, we find that the addressed intended MBs are insufficient for mitigating most of the *sanction*-focused unintended behaviors. While some of the formalized intended MBs related to *confirming process execution* (MB37-39), *capability building* (MB24), *instilling improvement mindset* (MB16) and *resolving ambiguities* (MB36) seem well-suited to mitigate the unintended behaviors *not exploring new solutions to solve problems* (UB02), *developing individual work routines* (UB06), *not following best known ways of working* (UB16), or *falling back on established procedures* (UB15), the remaining ones are not or only marginally addressed. For example, *blindly following procedures* (UB01) can only insufficiently be addressed by the MBs from the category *confirming process execution*, since that would require permanent monitoring of the operators. Similarly, *judging colleagues* can likely only in principle be addressed by MB20 (*foster inclusivity of thought and action*), since it is actionable only to a limited

extent. For other unintended behaviors such as *hiding behind perceived GMP limitations* (UB04) or *staying in comfort zone* (UB05) we do not find sufficient empirical evidence that would suggest they are formally addressed. MBs that could potentially mitigate UB04 include *routinely ask for SOP reference*, which seeks to reduce concerns that making changes may not be feasible due to potential SOP requirements. However, none of the existing MSW approaches has thus far formalized such practices of challenging concerns. Also, for UB05, we have not observed any MSW approaches, that would provide systematic incentive for shop floor personnel to overcome GMP-related barriers for OPEX if it is not driven by managers or by intrinsic motivation.

In conclusion, we find several shortcomings of existing MSW approaches with regards to addressing unintended behaviors. First, we find that while on an abstracted level the categories of UMEs could be addressed by existing MSW, the underlying unintended behaviors are only in parts formally addressed. On the one hand, this suggests a lack of comprehensiveness of the formalized MBs, which seems plausible given the substantial number of identified unintended MBs and the limitation of formalized standard MBs to one MSW approach. On the other hand, it suggests, that neither the formalized standard management interactions are comprehensive enough to address the identified unintended behaviors sufficiently. Second, we conclude that in terms of unintended behaviors, contextual factors are not sufficiently considered by existing MSW approaches. A reflection of unintended behaviors that are in parts driven by the contextual barriers identified in chapter 5.1 suggests that only those are addressed that are not exclusive to the pharmaceutical manufacturing environment. At the same time, we find that some of the MSW elements, such as *coaching* and *process confirmation*, are motivated in parts by contextual factors. We derive from it that while contextual factors are considered in the context of intended behavioral effects, they play only a subordinate role with regards to unintended effects. Finally, we find that particularly the unintended behaviors that concern either both SFB and MB or even only MB remain unaddressed. On the one hand, this iterates the critical role of managers for distorting unintended effects of MC. On the other hand, it highlights the importance of taking behavioral implications of MC comprehensively into account, not only in terms of SFB, but also in terms of organizational behavior more broadly.

Table 38: Unintended Behaviors Addressed by existing MSW Approaches

Focus of MB	Unintended Behavior (UB)	Behavior	Addressed via formalized MB
Communication	• Not highlighting or escalating problems	SFB	MB06
	• Application of visual systems on a limited scale	SFB & MB	N/A
	• Resistance to being open and transparent with visual systems	SFB & MB	N/A
	• Overemphasizing transmitting information to the neglect of supporting shop floor workers	MB	MB23
	• Not expressing concerns	SFB	N/A
	• Setting unrealistic goals	MB	N/A
	• Neglecting OPEX objectives	SFB	MB27
	• Focusing on wrong problems	SFB & MB	MB01
	• Rejecting relevant KPIs as inapplicable	SFB & MB	N/A
	• Acting in a reactive mode	MB	N/A
Power	• Monitoring of irrelevant metrics	MB & SFB	MB14
	• Hiding behind the quality system regarding creating transparency on performance	SFB & MB	N/A
	• Undercoaching	MB	MB22-24
	• Overcoaching	MB	N/A
	• Intervening quality organization	MB	N/A
	• Working in silos	SFB & MB	MB27
	• Not taking ownership for improvement	SFB	N/A
	• Not letting go of control	MB	N/A
	• Distrusting leadership of OPEX program	SFB	MB22
	• Focusing on certification	MB	N/A
	• Micromanaging shop floor activities	MB	N/A
	• Overemphasizing prior knowledge and assumptions	MB	N/A
	• Using training for punitive purposes	MB	N/A
	• Paralysis from complexity of situation	SFB & MB	N/A
Sanction	• Judging colleagues	SFB & MB	MB20
	• Sanctioning of deviations from goals	MB	N/A
	• Intervening in shop floor activities	MB	N/A
	• Blindly following procedures	SFB	MB37-39
	• Hiding behind perceived GMP limitations	SFB & MB	N/A
	• Not exploring new solutions to solve problems	SFB & MB	MB16, MB24, MB36
	• Developing individual work routines	SFB	MB37-39
	• Controlling standard work in same ways as SOPs	MB	N/A
	• Treating visual system as GMP structure	SFB & MB	N/A
	• Not following best known ways of working	SFB	MB37-39
	• Falling back on established procedures	SFB	MB16
	• Staying in comfort zone	SFB & MB	N/A

Next, we compare the three programs regarding the degree to which they integrate MSW and MC. Based on the formalized standard management interactions and the standard MBs we find that the six MC dimensions are only partially addressed by MSW of each of the three cases (cf. Table 39). Notably, *performance measurement* and *goal setting* are each only addressed by one of the programs. Further, *visualization* is not addressed by MSW of either of the three programs, even though PharmaCo F sees potential in linking MSW with *visual systems*. In contrast, all OPEX programs address

employee empowerment and *training* as part of MSW. Under the presumption that from a holistic perspective all six MC dimensions should be supplemented by MSW to comprehensively impact SFB, we conclude that MSW and MC are not fully integrated in the studied pharmaceutical OPEX programs.

Table 39: Overview of MC Dimensions addressed by MSW

Addressed MC Dimension	PharmaCo A	PharmaCo C	PharmaCo F
Standardized Work		•	•
Visualization			
Performance Measurement		•	
Employee Empowerment	•	•	•
Goal Setting	•		
Training	•	•	•

The comparison of the addressed MC dimensions suggests that only PharmaCo C exploits all three types of control, namely *input control*, *process control* and *output control*. Specifically, we find that *confirming key outputs* represents the only formalized MSW component that focuses on the *output* to impact SFB. In contrast, PharmaCo A addresses *input control* and *process control* formally, whereas PharmaCo F only covers *process control*. On the example of PharmaCo F we note that while *training* can be viewed as a mean to exert *input control*, accounting for *coaching* in the process as part of MSW requires a more nuanced perspective. From the case interviews we find that PharmaCo F has only formalized *coaching* during the process as part of MSW. In contrast, PharmaCo A and PharmaCo C also include *coaching* on the *input* side as part of MSW. In these cases, managers with respective coaching roles are expected to routinely contribute to continuous *coaching* of shop floor personnel and colleagues by developing and conducting learning sessions that are disconnected from process execution.

Finally, we can derive differences with regards to role-based interactions from comparing the organizational embedding of MSW between the three OPEX programs. All three companies differentiate different roles as part of the standard management interactions by distinguishing two different *coaching* roles (coach and coach of coach) and the role of the practitioner. PharmaCo A, for example, defines role-based tasks for both of its standard management interactions *problem solving* and *coaching* and

distinguishes for each between problem solver, coach and coach of coach. While the role-based tasks for *problem solving* are initiated based on specific incidents or problems and therefore happen during the *process*, the standard management interaction *coaching* is disconnected from specific shop floor activities. PharmaCo C, on the other hand, distinguishes to types of coaching that happen during the *process* with a focus on unlocking the potential of an individual or ensuring adherence to standards. Since personal development in the form of the former can be viewed as one means for *employee empowerment*, which we conceptualize as an *input control*, we conclude that with a respective focus, also coaching during the process, can act as a mean for *input control*. The time or place where MC is exerted, therefore, seems not enough to exclusively assign it to either of the three types of control.

5.2.5 Implications

In the previous chapters, we illustrate how three pharmaceutical OPEX programs apply MSW to impact SFB. We also elaborate on the underlying formalized standard MBs and standard management interaction for affecting intended MB and we establish a link between the intended MBs as well as the derived unintended consequences of MC that these can potentially address. Finally, we outline how MSW and MC can supplement each other, as illustrated by the three studied MSW examples.

To model the interaction between MSW, MB and SFB from a structuration perspective, we draw on (Macintosh & Scapens, 1990) conceptualization of structuration, analogously to chapter 5.2.1. MSW with its components that define standards can be viewed as representing *structure*, as it formalizes management conduct to guide MB (cf. *Figure 25*). In contrast, the actual MB represents the behavioral component *interaction*. Finally, MB and MSW can be modeled as being interconnected via intended respectively unintended consequences. In the context of impacting SFB with MB, these can be viewed as desired respectively undesired SFB.

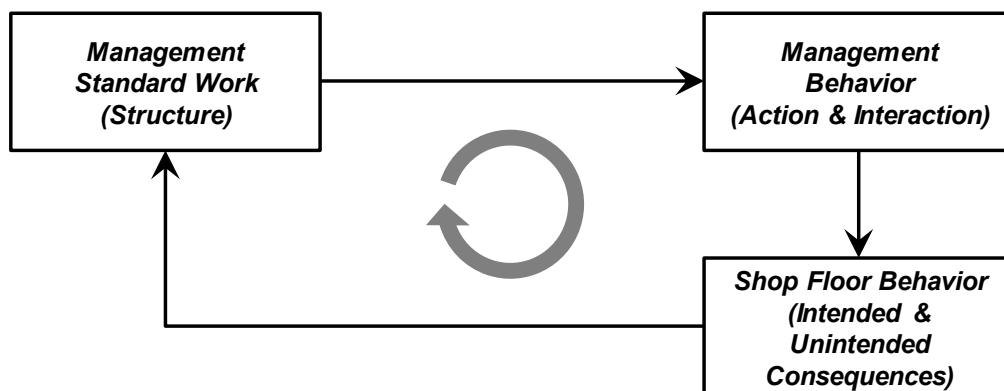


Figure 25: Simplified Management Behavior Loop, adapted from (Macintosh & Scapens, 1990)

Based on the derived potential of the intended MBs to address all the 25 identified unintended effects, the findings support the view that MB plays a central role for mitigating potential unintended consequences of management control as part of pharmaceutical OPEX programs. Thus, it is concluded that adequately impacting SFB with OPEX programs requires not only optimized management control systems, but also adequate MSW that systematically supplements management control based on formalized intended MBs.

Figure 26 maps the interrelation between the formalized MBs and each of the six MC dimensions, based on the potential of each MB sub-category to mitigate the identified unintended MC effects. Our mapping suggests that each pool of MBs that is associated

with either of the three MB dimensions *communication*, *power*, and *sanction* can affect all six MC dimensions in terms of mitigating various unintended MC effects. In order to comprehensively impact SFB in desired ways, pharmaceutical manufacturers should therefore pay close attention to MBs from all three dimensions. At the same time, the three studied cases do only partially support the six dimensions MC with MSW, thereby indicating potential for further integration of MC with MSW (cf. *Table 39*).

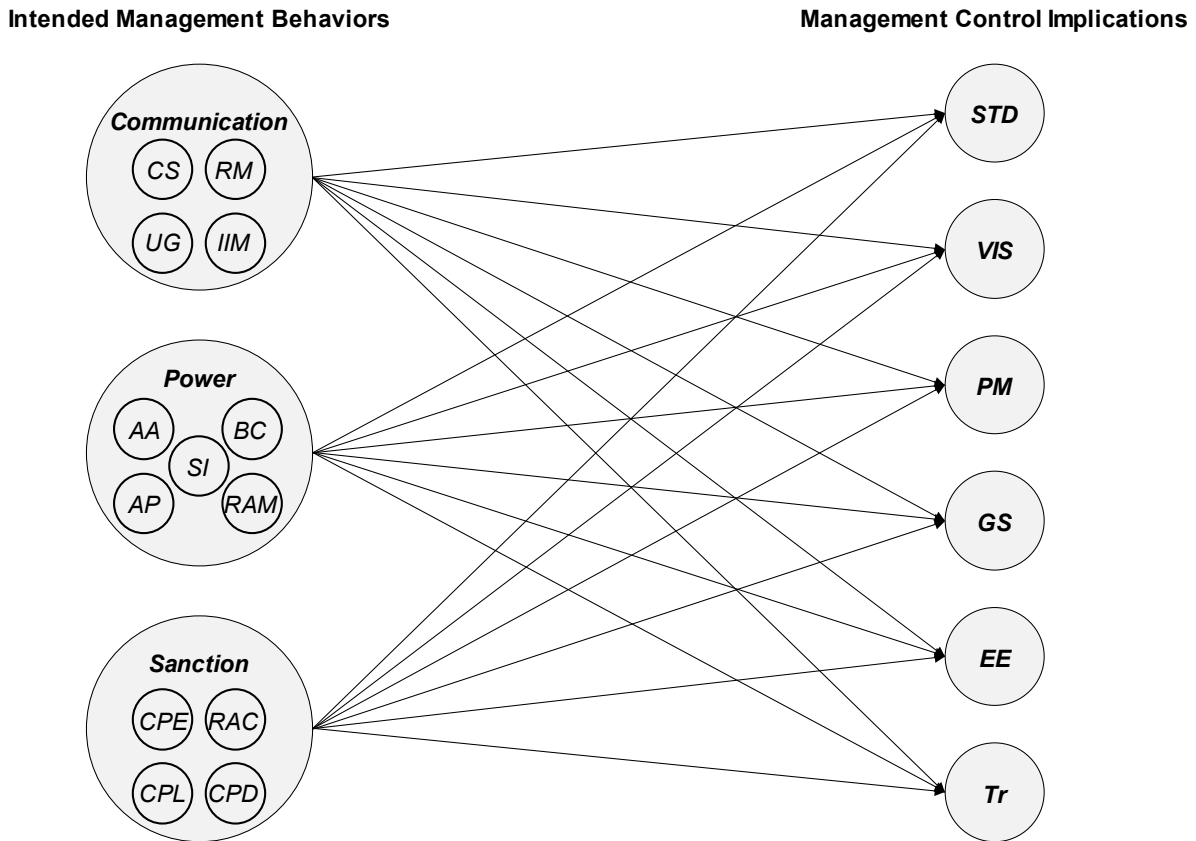


Figure 26: Management Control implications of intended MBs

The findings outlined above further suggest that all the identified unintended MC effects can be addressed to some extent by the pool of identified MBs. While the degree to which they can be eliminated and potential interaction effects are not further investigated as part of this research, we can conclude that the derived intended MBs can individually in fact support each of the relevant MC dimensions by mitigating unintended MC effects. We therefore confirm the hypotheses H2a to H2f.

H2a: *OPEX Management behaviors exist that can support employee empowerment in pharmaceutical firms.*

H2b: *OPEX management behaviors exist that can support training in pharmaceutical firms.*

H2c: *OPEX management behaviors exist that can support goal setting in pharmaceutical firms.*

H2d: *OPEX management behaviors exist that can support standardized work.*

H2e: *OPEX management behaviors exist that can support visualization in pharmaceutical firms.*

H2f: *OPEX management behaviors exist that can support performance measurement in pharmaceutical firms.*

Notably, while each of the MC dimensions can be supported on the basis of the identified management behaviors, the findings further reveal that practitioners do not link the supportive management behaviors to the MC dimensions, even though both are often explicitly recognized as key success factors for OPEX. Thus, MC and management behaviors are often treated as isolated means, even though they can jointly impact SFB. The outlined interconnected behavioral implications of both MC and management behavior are therefore if at all only available as implicit knowledge and typically only to experienced OPEX practitioners or mature organizations that have been able to identify successful behaviors over time without conceptualization knowledge of their direct or indirect effects.

A comparison of the MB categories formalized as part of the studied OPEX programs shows that neither company applies all thirteen MB categories (cf. *Table 37*). Notably, neither company formalizes MBs that are suited to mitigate unintended behaviors resulting from MC in the context of the identified barriers *procedural regulation*, *design of SOPs for regulatory use*, *separation of quality from OPEX*, and *compliance trap* (cf. chapter 5.1). In contrast, all three cases comprise MSW components that can mitigate the unintended behavior *undercoaching* (UB23), which highlights the critical role of managers as coaches in pharmaceutical manufacturing. Finally, we find that of the identified a pool of intended MBs only roughly half are formalized in the companies that have embedded MSW in their OPEX programs. As a result, more than half of the identified unintended behaviors that can potentially result from MC are not addressed by MSW of the studied companies.

In addition to establishing the critical role that MB can play for impacting SFB, our findings highlight the need to distinguish between unintended and intended MC effects for impacting SFB, similarly to (Macintosh & Scapens, 1990) conceptualization. The unintended MC implications, on the one hand, should be mitigated or eliminated. Theoretically, this can be achieved by either enhancing applied MC or by applying supportive MB. Examples for adjustments of MC include enhancing SOPs for ease-of-use (*standardized work*) by making them more visual. By the same token, the intended MC effects should be strengthened by integrating MC and MSW.

From the conducted expert interviews, we find that, to date, the mitigation of unintended MC effects plays only a marginal role for MSW in the studied OPEX programs. Instead, MSW is applied primarily with a focus on realizing intended effects. Furthermore, our empirical analysis suggests that the studied cases do not conceptually distinguish between intended and unintended consequences of MC either. However, based on the unintended behaviors that are currently not addressed by existing MSW (cf. *Table 38*), we believe that such a conceptual distinction would be necessary to comprehensively support MC with MB.

Drawing on (Macintosh & Scapens, 1990) and based on the implications outlined above, we conclude that a comprehensive model for impacting SFB should satisfy the following criteria: First, it should conceptualize MC and MB as interrelated levers for impacting SFB. Next, it should account for the dual role that MB can play for supporting MC, in terms of strengthening intended MC effect on the one hand and mitigating unintended MC effects on the other hand. Finally, it should account for the complex interrelations between behavioral and structural aspects within an integrated model.

By combining the two previously outlined loops depicted in *Figure 20* and *Figure 25*, we can assemble a simplified model for impacting SFB with MB, which satisfies the criteria outlined above (cf. *Figure 27*). In accordance to the conceptualization of MC and MB as key levers for impacting SFB, it involves two interrelated loops. We coin the one loop the MB loop and the other one the MC loop, both of which cover components that represent *structure* and *interaction*. Following our definition of MC, the MC loop focuses on directing SFB based on structural aspects that are independent from actual manager conduct. To account for the critical role that managers play for impacting SFB, the MC loop is supplemented by the MB loop, in which MSW guides actual MB, which in turn affects SFB. Both loops are connected via SFB, which can be viewed as the dependent factor for both loops. Finally, the model accounts for the importance of a continuous mitigation and strengthening of unintended respectively intended effects of both MC and MSW for impacting SFB.

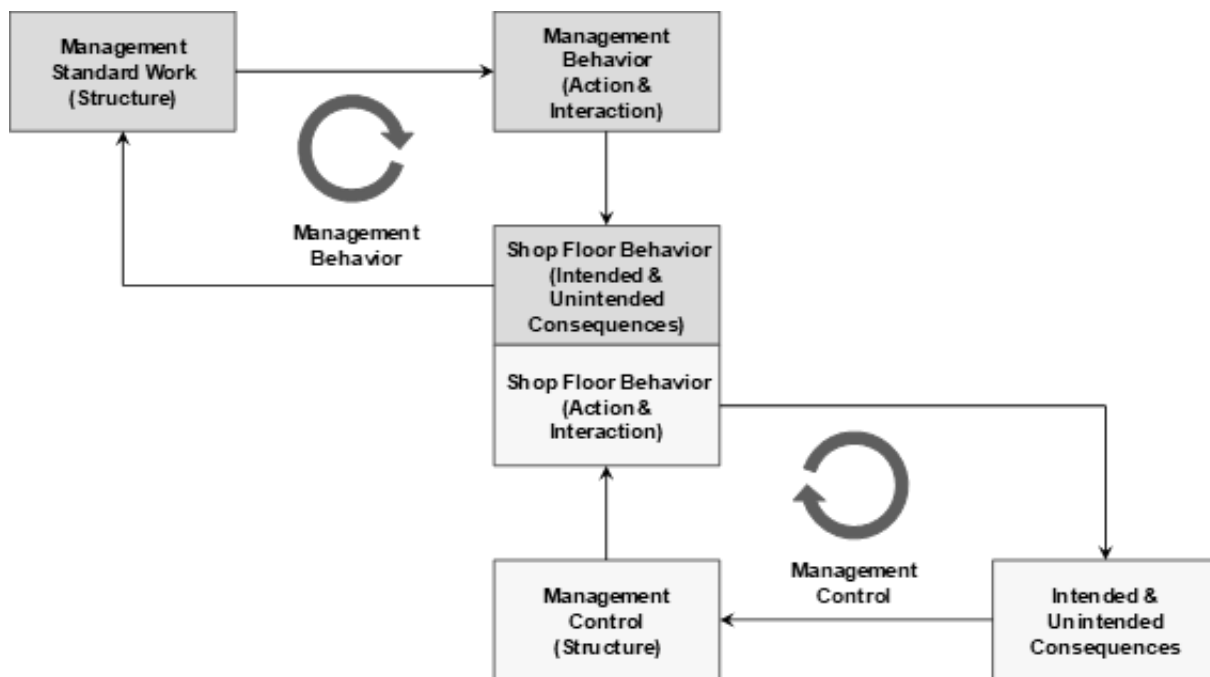


Figure 27: Double-loop model for impacting shop floor behavior

5.3 Performance Effects of Management Control

To study the measurable effects that MC has on the relation between operations-oriented OPEX practices and operational performance in pharmaceutical manufacturing, first, test the constructs that are developed for the quantitative analysis are tested for validity and reliability (chapter 5.3.1). Next, correlation analysis is conducted to gain insights into the interrelations between the components of both the MC constructs and the developed performance measurement (chapter 5.3.2). The subsequent hierarchical linear regression analysis seeks to identify the performance effects of the relevant MC constructs (chapter 5.3.3). Finally, the results from this quantitative analysis are discussed (chapter 5.3.4). The analyses presented in the following is in parts adapted from (Macuvele et al., 2020).

5.3.1 Construct Validity and Reliability

Validity of MC constructs is tested using CFA and following (Hair et al., 2006).

The factor loadings of all measurement items meet the threshold for one-dimensionality suggested by the authors. Except for one item at 0.42, all factor loading further exceed 0.5 (Table 40). The CFA results further indicate good convergent validity for all six MC

constructs, with values for composite reliability (CR) and the average variance extracted (AVE) exceeding the recommended thresholds $CR > 0.7$ respectively $AVE > 0.5$.

In addition to validity, the calculated Cronbach's α further indicate satisfactory construct reliability, with values exceeding 0.7 for each construct. Finally, the developed factor model shows good model fitness in terms of Comparative Fit Index ($CFI = 0.95$), Root Mean Square Error of Approximation ($RMSEA = 0.056 < 0.08$) as well as χ^2 test ($\chi^2/df = 1.994 < 3$).

In conclusion, the CFA results provide quantitative support for the literature-based conceptualization of the six MC dimensions as distinct constructs. The analysis results further suggest that the eighteen items used to measure the six MC constructs depict adequate measurement items. The six developed MC constructs therefore depict suitable measurements that can be used in the following to quantitatively study the performance effects of MC for our research context.

Table 40: CFA results for the developed MC constructs

Construct	Item	Factor loading CFA	Composite Reliability (CR)
Visualization	VIS1	0.793	0.819
	VIS2	0.842	
	VIS3	0.702	
	VIS4	0.419	
Standardized work	STD1	0.655	0.772
	STD2	0.733	
	STD3	0.792	
Performance Measurement	PM1	0.666	0.758
	PM2	0.886	
Employee Empowerment	EE1	0.790	0.763
	EE2	0.633	
	EE3	0.732	
Goal Setting	GS1	0.764	0.799
	GS2	0.779	
	GS3	0.722	
Training	TR1	0.773	0.804
	TR2	0.922	
	TR3	0.559	

Next, the PCA results suggest that the eleven categories of TPM, TQM and JIT practices depict adequate components for measuring the implementation of operations-oriented OPEX practices with a single score. The resulting score can therefore be used in the following as the independent variable of the subsequent linear regression analysis as part of this research.

Table 41 shows that factor loadings of all eleven components are above the recommended threshold of 0.4. These findings confirm that the eleven subcategories as adequate components of the developed construct. This is in line with existing OPEX literature that identifies the eleven categories as critical components of the OPEX operating system (Cua et al., 2001). The PCA results further reveal that the one factor model explains 40.01 % of the variation, which indicates, among others, that the subcategories can be meaningfully represented by the single-score construct. Finally, PCA shows a Cronbach's α of 0.842, with a component eigenvalue of 4.40, indicating adequate construct reliability.

Table 41: PCA results for the construct of aggregated operations-oriented OPEX practices

			Component ^a		
			Mean	S.D.	Operations-oriented practices
JIT	Set-up time reduction	2.91	0.74	0.771	
	Pull system production	2.78	0.64	0.526	
	Equipment layout	3.04	0.81	0.665	
	Schedule adherence	3.50	0.67	0.727	
TQM	Process management	3.20	0.79	0.736	
	Cross-functional product design	3.39	0.93	0.558	
	Supplier quality management	3.35	0.62	0.522	
	Customer involvement	3.60	0.74	0.497	
TPM	Autonomous and planned	3.55	0.68	0.665	
	Technology emphasis	2.88	0.72	0.639	
	Housekeeping	3.92	0.86	0.578	
Eigenvalue (variance explained)				4.40 (40.01%)	
Cronbach's α				0.842	

^a Extraction method: Principal component analysis

5.3.2 Correlation Analyses

5.3.2.1 Management Control Dimensions

A correlation analysis of the six MC dimensions, suggests that they are strongly interrelated. *Table 42* suggests that all correlations are highly significant ($p < 0.01$). In addition, all correlations are positive, indicating that higher implementation levels for one construct are associated with higher implementation levels of another.

A comparison of the correlation coefficients shows that *goal setting* is correlated the strongest with other MC constructs. Notably, four out of the five highest correlation pairs involve *goal setting*, which has an average correlation coefficient of 0.638. In

contrast, *training* shows on average the lowest correlation with other MC constructs, with average correlation coefficient of 0.383. A comparison of the mean implementation levels for each construct further indicates that *goal setting*, *performance measurement*, and *standardized work* depict the three MC dimensions with the highest degree of implementation. In this context, *visualization* represents the only dimension with a mean implementation below the value of 3.

Table 42: Correlation between the dimensions of MC

Construct		Mean	S.D.	VIS	STD	PM	EE	GS	TR
Visualization	VIS	2.894	1.006	-					
Standardized work	STD	3.657	0.800	.471**	-				
Performance Measurement	PM	3.877	0.933	.510**	.529**	-			
Employee Empowerment	EE	3.582	0.858	.673**	.530**	.567**	-		
Goal Setting	GS	3.964	0.779	.650**	.646**	.661**	.687**	-	
Training	TR	3.381	0.784	.441**	.489**	.363**	.461**	.544**	-

**Significant at the $p < 0.01$ level

5.3.2.2 Performance Measures

Using real performance data from pharmaceutical manufacturers, a correlation analysis of the metrics that make up the operational performance score provides insights into the actual relations between quality, dependability, speed or cost performance. Among others, the results suggest that metrics representing different performance dimensions can be both significantly positively and negatively correlated (Table 43).

First, the results indicate that customer complaint rate and rejected batches are significantly positively correlated. The two facets of quality performance that are represented by these metrics, namely internal and external quality, can therefore be viewed as being interrelated. Plants that achieve high quality therefore likely perform well with regards to both metrics.

Analogously, in terms of dependability, the correlation results indicate that production schedule adherence and on-time delivery, as measures of internal respectively external delivery dependability, are also significantly positively correlated. Accordingly, increased internal dependability also appears to translate into superior external delivery performance.

Third, the correlation analysis indicates that the two metrics representing inbound and outbound inventory levels are significantly interrelated. The analysis suggests that plants with high finished goods inventories are more likely to also have larger stockpiles of raw material.

Finally, the correlation results indicate various interrelations between cost performance on the one hand and quality, delivery as well as speed performance on the other hand. First, finished good turns as a measure of outbound inventory levels and on-time delivery are significantly negatively correlated. This could be explained by make-to-stock fulfillment strategies, which seek to achieve high levels of on-time delivery by keeping high levels of finished goods on stock. Second, speed in terms of both short deviation closure time and delivery in terms of production schedule adherence is significantly correlated with low inventory levels. While high on-time delivery can be achieved at the expense of increased finished good inventory, as outlined above, short deviation closure time bears the potential to lower inventory levels. Possible explanations include that it reduces the feasible product release times and thereby production lead times, which in turn reduce the need for excess inventory. Similarly, the results suggest that production schedule adherence is associated with lower levels of raw material turns, which could be explained by more reliable consumption of material. Third, better quality performance in terms of rejected batches appears to be associated with better cost performance regarding raw material and finished goods inventories. Considering that high numbers of rejected batches can result in scrap and increased material consumption, the positive correlation with each raw material turns and finished good turns could be explained.

In conclusion, the correlation analysis provides empirical support for using the selected set of metrics to measure balanced operational performance. Although the metrics do not aspire to form unidimensional components, since we are interested in measuring real and balanced operational performance, they can be viewed as representing internally consistent facets of performance in pharmaceutical manufacturing. Further, including multiple metrics to measure quality, dependability and cost in the operational performance score allows for a more granular performance assessment, since they describe different aspects of performance. Finally, the analysis of the real performance data suggests that plants can plausibly achieve high levels of operational performance with regards to all underlying metrics, given the mostly positive or indifferent correlation coefficients.

Table 43: Correlation between relevant operational performance metrics

Measurement	Mean	S.D.	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
(1) Rejected batches	0.522	0.299	–							
(2) Customer complaintrate	0.515	0.296	.118**	–						
(3) Unplanned maintenance	0.522	0.286	0.020	0.049	–					
(4) Production schedule adherence	0.459	0.279	0.089	-0.064	-0.023	–				
(5) On-time delivery	0.477	0.280	0.065	0.035	-0.019	.281***	–			
(6) Deviation closure time	0.522	0.287	0.007	0.005	-0.065	0.019	-0.031	–		
(7) Raw material turns	0.490	0.294	.132**	0.053	-0.039	.281***	-0.044	.182**	–	
(8) Finished good turns	0.495	0.292	.134**	-0.093	-0.092	0.006	-.242***	.214**	.346***	–

* $p < 0.1$; ** $p < 0.05$; *** $p < 0.01$.

5.3.3 Hierarchical Linear Regression Analysis

Using standardized values for the independent and moderator variables to address multicollinearity (Aiken & West, 1991), three regression models are calculated to study the performance effects of MC in the context of OPEX programs. The first model takes only the effects of control variable on operational performance into account in order to evaluate their performance impact. The second model additionally considers the direct effects of both operations-oriented OPEX practices as well as the six MC constructs on operational performance. The third model adds interaction terms between the aggregated score of operations-oriented OPEX practice score and each of the six MC constructs to study indirect effects of MC on operational performance.

Table 44 provides an overview of the hierarchical linear regression results based on unstandardized regression coefficients, due to prior standardization of the moderation variables. It shows, among others, that all three models are significant. In addition, it shows that the inclusion of operations-oriented OPEX practices as well as MC contribute significantly to increasing the variance that can be explained.

Based on the first model, the regression results show that contextual factors by themselves only explain a marginal amount of variance in performance outcome (3.8%). Additionally, of the relevant contextual factors only plant size and plant type appear to have an impact on operational performance.

The second model suggests that including direct effects of both operations-oriented OPEX practices and MC significantly increases the variance that can be explained to 16.2%. It further suggests that the implementation level of operations-oriented OPEX practices has a strong and significant direct performance effect that is positive. The six MC dimensions, on the other hand, appear to not have significant direct effects on operational performance.

Table 44: Results of linear hierarchical regression analysis

	Model 1	Model 2	Model 3
Size	-0.001**	-0.001***	-0.001***
Brand Manufacturer	0.237	0.093	0.206
Generics Manufacturer	-0.015	-0.017	-0.023
Contract Manufacturing Organization	-0.502**	-0.330	-0.319
Operations-oriented OPEX practices (OOP)		0.361**	0.387***
Visualization (VIS)		-0.077	-0.129
Standardized work (STD)		0.071	0.058
Performance Measurement (PM)		0.126	0.179*
Employee Empowerment (EE)		0.075	0.116
Goal Setting (GS)		-0.083	-0.142
Training (TR)		0.109	0.076
OOPxVIS			0.259**
OOPxSTD			-0.292***
OOPxPM			0.171*
OOPxEE			0.290**
OOPxGS			-0.221*
OOPxTR			-0.113
Adj. R2	0.038	0.162	0.231
ΔR^2	0.060	0.153	0.091
F-value	2.788	4.674	3.539
P-value of F statistic	0.028	0.000	0.003

* $p < 0.1$; ** $p < 0.05$; *** $p < 0.01$.

The third model suggests that the additional inclusion of indirect effects of MC in terms of interaction with operations-oriented OPEX practices further improves the model. Like the second model, it suggests that operations-oriented OPEX practices have a strong and significant positive performance effect ($p < 0.01$). With exception of *performance measurement*, it also suggests that MC has no significant direct effect on operational performance. Notably, the model suggests that all MC dimensions, but *training* significantly affect operational performance indirectly through interaction with operations-oriented OPEX practices. The results suggest that the interaction effects of *visualization*, *performance measurement*, and *employee empowerment* on performance are significant and positive, whereas *standardized work* and *goal setting* show significant negative performance effects. Finally, by adding interaction terms between

MC and operations-oriented OPEX practices as independent variables to the regression model, the variance that can be explained is increase to 23.1%.

After calculating the hierarchical linear regression model, the proposed research hypotheses can be evaluated. As the third model is significant and it further explains the highest variance in performance outcomes the following four hypothesis for the quantitative analysis can be confirmed.

H3: *The application of operations-oriented OPEX practices is positively associated with the operational performance of pharmaceutical manufacturing firms*

H4a: *Employee empowerment positively moderates the relationship between the application of operations-oriented OPEX practices and operational performance.*

H4e: *Visualization positively moderates the relationship between the application of operations-oriented OPEX practices and operational performance.*

H4f: *Performance measurement positively moderates the relationship between the application of operations-oriented OPEX practices and operational performance.*

The following three hypotheses cannot be confirmed. On the one hand, *training* does not show significant moderation effects. In fact, no significant direct or indirect performance effects of *training* can be shown using regression analysis.

H4b: *Training positively moderates the relationship between the application of operations-oriented OPEX practices and operational performance.*

On the other hand, for both *goal setting* and *standardized work* the analysis results suggest significant moderation effects, but negative ones. Since, from an OPEX perspective, counterproductive effects seem to have the upper hand for these two MC dimensions in the studies pharmaceutical manufacturing firms, the respective hypotheses can only inversely be confirmed and are therefore dismissed.

H4c: *Goal setting positively moderates the relationship between the application of operations-oriented OPEX practices and operational performance.*

H4d: *Standardized work positively moderates the relationship between the application of operations-oriented OPEX practices and operational performance.*

5.3.4 Discussion of Performance Effects of Management Control

Moderation effects

The identified significant moderation effects provide empirical support for the need to adopt a more integrative perspective on the performance effects of operations-oriented and people-oriented OPEX practices. With one exception, MC affects operational performance only indirectly through moderating effects. This suggests that their performance effects reside in the effective implementation of operations-oriented OPEX practices. In contrast, existing OPEX research focuses on direct performance effects of these practices, despite people-oriented OPEX practices being conceptualized in recent study as supportive OPEX practices (Hadid & Mansouri, 2014). Their performance effects are usually considered independent from the implementation of other OPEX practices, such as operations-oriented practices, even though such supportiveness is not necessarily limited to direct effects.

The lack of widespread direct performance effects of MC suggests that the degree to which respective MC dimensions are implemented does not by itself determine the operational performance of a site. An isolated adjustment of the MC system will therefore likely not contribute to enhanced operational performance. Based on the rather generic intended MC effects (e.g. *acting on improvement opportunities*) such view appears appropriate especially since the same intended effects can be achieved based on different MC dimensions (cf. 3.3). The findings therefore suggest that without taking additional aspects into account that affect the activities on the shop floor, the implementation levels of respective MC dimensions do not sufficiently differentiate pharmaceutical plants in terms of their ability to achieve high operational performance.

Taking interaction effects with operations-oriented OPEX practices into account, supports the view that, in conjunction with relevant contingency factors, the studied MC dimensions can have significant performance effects. In combination with the direct and positive performance effects of operations-oriented OPEX practices, the significant interaction effects suggest that MC moderates these performance effects. These interaction effects can be interpreted based on the derived underlying behavioral mechanisms that the relevant MC dimensions can influence. To illustrate, as outlined in chapter 5.2.2, the two MC dimensions *employee empowerment* and *visualization* can affect *enablement* in terms of a qualified workforce or *discipline* of shop floor personnel to act in desired ways. These intended behaviors can include, among others, effective utilization of operations-oriented OPEX practices. The effectiveness of set-up time reduction or layout optimization, for example, will likely depend on the competencies

and the willingness of the personnel that is involved in these tasks daily. Similarly, the effectiveness of other operations-oriented practices can be affected by influencing *motivation* and *focused attention* of shop floor workers.

Bidirectional performance effects

The regression results provide empirical support that a more critical attitude is appropriate towards conventional OPEX wisdom that assumes net positive effects of MC as part of OPEX programs. The findings concerning the direct performance effects of operations-oriented OPEX practices correspond well to empirical OPEX research. However, the shown partially negative moderating effects of MC suggest that some aspects of MC do not by definition contribute to better performance. The negative moderating effects even suggest that less *standardized work* and *goal setting* would increase operational performance in pharmaceutical manufacturing.

Based on the intended and unintended MC effects that are derived as part of this research, the bidirectional performance effects can be interpreted in terms of supportive respectively counterproductive behavioral effects of MC. From this perspective, performance effects of MC are likely contingent upon organizational peculiarities. In contrast, the interpretation that MC dimensions that show negative performance effects are generally counterproductive for OPEX is not considered viable. Such interpretation would conflict not only with the qualitative findings of this research, but also with existing OPEX and MC research that suggests potential benefits from these MC dimensions (cf. chapter 3.3).

Potentially relevant context factors can include, among others, industry type, OPEX maturity levels, plant size, or organizational embedment of MC. Since the regression results indicate significant positive and negative moderation effects across a large sample of 351 pharmaceutical plants with different sizes, product focus, regional footprint and OPEX maturity levels, the underlying reasons for negative performance effects could on the one hand be found in the commonalities among all plants. The overarching one being their affiliation with the regulated pharmaceutical manufacturing. Associated with that are joint exposure to the identified contextual barriers for impacting OPEX behavior, relatively short history with OPEX compared to other industries. Another potential commonality could be the way MC is organizationally embedded, which is not necessarily related to a specific industry.

Since the regression results suggest significant positive performance effects of the operations-oriented OPEX practices, a lack of OPEX know-how due to shorter OPEX history may not be the reason for counterproductive effects from applying MC.

However, unintended consequences of MC due to other organizational peculiarities continue to depict viable underlying reasons for the partially negative effects of some MC dimensions.

The finding that some MC dimensions show significant positive moderating effects, while others show negative ones or none at all suggests that taking interaction effects with operations-oriented OPEX practices into account alone is insufficient to fully interpret behavioral implications of MC for OPEX. Among others, the regression analysis does not provide insights into the impact of further potentially relevant organizational peculiarities. Based on the conducted qualitative empirical research, potentially relevant organizational peculiarities include contextual barriers, organizational embedment of MC, or applied MBs. As a result, the complex socio-technical interactions in OEPX programs in general, as well as the complex behavioral effects of MC in particular that are emphasized in OPEX literature respectively in MC literature can only be evaluated quantitatively to a limited extent as part of this research.

An interpretation attempt of the negative performance outcomes of *standardized work* and *goal setting* could involve the identified intended and unintended effects of MC. Both represent the only dimensions that focus on facilitating intended behaviors related to *adherence to standards* (cf. Table 12). From a structuration perspective, both are therefore essential for sanctioning inadequate behavior. In this capacity, both play a critical role as key means for instilling *discipline*. In contrast to, for example, increasing *motivation*, or *enablement*, the focus on *adherence to standards* therefore carries the risk that intended productive efforts for OPEX turn into counterproductive command-and-control mechanisms. Since both further do not seek to facilitate those behaviors that increase employee engagement by helping them with *identifying root causes*, *timely and independent decision making*, and *acting on improvement opportunities*, both can be viewed as more likely than the other MC dimensions to disengage shop floor workers from continuous improvement. Since negative performance effects can be expected, when the counterproductive effects outweigh the productive effects, both can as a result further be considered more likely than others to cause negative performance effects. A possible pharma specific interpretation attempt could further take the derived contextual barriers into account, which comprise a variety of barriers that can specifically hinder employee engagement in continuous improvement. These barriers can play an additional role in determining whether productive or counterproductive effects of MC prevail in pharmaceutical manufacturing.

Finally, the quantitative results support the conceptualization of some people-oriented OPEX practices as dimensions of MC. To illustrate, both the dependence of

performance effects on the implementation of operations-oriented OPEX practices as well as the bidirectional performance effects can be interpreted from a MC perspective. First, MC can affect how shop floor workers interact within the OPEX operating system. As a result, MC can influence the degree to which operations-oriented OPEX practices are utilized effectively. On the other hand, depending on the situated behavioral implications of MC, both productive and counterproductive effects are feasible as illustrated based on the derived intended and unintended consequences of MC in pharmaceutical manufacturing. The possibility of partially negative performance effects of MC is therefore consistent from a MC perspective, as MC literature takes complex behavioral implications of MC, including counterproductive ones, into account. In contrast, accounting for such effects based on existing OPEX literature would require a shift towards a more differentiated view on people-oriented practices, as existing OPEX research commonly assume that respective people-oriented OPEX practices are generally beneficial.

5.4 Framework for Impacting Shop Floor Behavior

In the following, an integrated framework for impacting SFB with pharmaceutical OPEX programs is developed. The framework seeks to extend the existing OPEX literature on human behavior management in two ways. First, by bringing together relevant determinants of SFB in one process model. Second, by describing the relations among these, by integrating insights from both existing OPEX research and our empirical research on pharmaceutical OPEX programs. The resulting framework represents a theoretical model for impacting SFB, which makes the assumed relationships between the determinants of SFB explicit. It can be used to guide organizational efforts for impacting SFB, or to evaluate, in retrospect, the impact of relevant determinants of SFB.

5.4.1 Logic Model Approach

Impacting SFB with OPEX programs can be viewed as a complex social intervention. Complex interventions can be characterized by non-linearity, emergent and uncertain outcomes, reinforcing loops, interactive structures and relationships, as well as disproportionate¹⁶ outcomes (Glouberman & Zimmerman, 2002; Rogers, 2008). The complex nature of impacting SFB can be illustrated, among others, by the interrelatedness of the identified determinants of SFB, including MC, MSW, MB and contextual barriers. It can also be considered a complex intervention from a structuration perspective, based on the underlying conceptualization of behavior in social systems as both the medium and the outcome of structuration.

To construct a framework for impacting SFB with OPEX programs, this research draws on program evaluation research and, more specifically, on program theory evaluation. It provides a framework for theory-driven evaluation of program effects, which can be used to conceptualize and evaluate complex social interventions.

Program theory evaluation represents an alternative to black-box program evaluation, which solely focuses on analyzing whether or not a program causes an effect, without analyzing how the effect is achieved (H.-T. Chen, 1990). Black-box evaluations rely on randomization of the analyzed test groups to ensure validity, according to (H.-T. Chen & Rossi, 1987). Unlike the method-driven black-box evaluation approach, program theory evaluation builds upon a theory-driven framework to deal with validity

¹⁶ In complex systems, large effects can occur from small interventions through reinforcing loops and critical tipping points Rogers (2008).

issues (H.-T. Chen & Rossi, 1987). Not relying on randomization to ensure validity can be viewed as a benefit of program theory evaluation, since adequate test group randomization poses a practical challenge in complex social systems. In addition to evaluating program effectiveness, program theory evaluation further allows to derive insights on underlying causative relationships between program measures and its effects, in addition to evaluation of program efficiency. Further potential benefits of program theory approach can be derived from (Rogers, 2008). The author provides a framework for classifying different aspects of complexity, including non-linearity, that can be addressed by program theory. According to (Rogers, 2008), program theory evaluation facilitates conceptualizing and evaluating linear or dynamic models with multiple determinants as well as with both unidirectional, or multidirectional causative relationships. Given the lack of linear cause-and-effect relations that is highlighted in the existing OPEX literature as a potential OPEX barrier (cf. chapter 2.1), the program theory approach seems well-suited for constructing a framework to address our research problem.

A program theory represents the starting point for program theory evaluation. It can be defined as “a specification of what must be done to achieve desired goals, what other important aspects may also be anticipated, and how these goals and impacts are to be generated” (H.-T. Chen, 1990, p. 9). According to the author, this definition reflects the synthesis of descriptive theory and prescriptive theory. On the one hand, it seeks to prescribe the structure and measures a program should include. On the other hand, it seeks to evaluate the actual mechanisms that link program with its achieved outcome. Following this definition, (H.-T. Chen, 1990) proposes that program theory can be categorized into two sub theories. These are the normative theory and a causative theory, which in conjunction form the basis for six types of theory-based evaluations (cf. *Table 45*). The normative theory provides guidance on how a program should be designed and implemented and what should be achieved and thus examined. More generally, it prescribes how a program is understood to work. The causative theory, on the other hand, provides a basis for examining the mediating mechanisms that underly the assumed effects, the preconditions under which these effects may arise, as well as their likely consequences. Both theories provide a theoretical foundation for evaluating how a respective program works, by making assumed cause-and-effect relationships explicit.

Table 45: Program theory and evaluation types (H.-T. Chen, 1990)

Sub theory	Evaluation Type	Description
<i>Normative Theory</i>	Normative program evaluation	Identifies the normative structure of the program, examines the actual program delivered in the field, and assesses the congruence between normative and implemented program.
	Normative implementation environment evaluation	Identifies the normative implementation environment, examines the actual environment in which the program is implemented, and assesses the congruence between the normative and the actual implementation environments.
	Normative outcome evaluation	Seeks to identify the set of normative goals or outcomes to be pursued or examined by the program. It further ascertains whether the resources and program activities are oriented toward these goals or outcomes for facilitating program planning management.
<i>Causative Theory</i>	Impact evaluation	Examines a broad base of evidence to assess program impact in terms of both plausible intended and unintended outcomes.
	Intervening mechanism evaluation	Examines the underlying process mediating between program and outcome.
	Generalization evaluation	Considers how to extend the immediate evaluation results to future situations of interest to the stakeholders.

The purpose of developing our framework for impacting SFB is aligned with distinct aspects of the sub theories. On the one hand, we seek to address the proposed need to adopt an integrated perspective on human behavior management in the context of OPEX programs, by taking the identified determinants of SFB into account in an integrated and comprehensive manner (normative theory). On the other hand, we seek to provide guidance for supporting the design, implementation and sustainment of OPEX programs by constructing a basis for examining the mechanism that mediate the process of impacting SFB (causative theory). Thus, of the six evaluation types outlined above, our framework primarily aims at facilitating normative program evaluation, normative implementation environment evaluation as well as intervening mechanism evaluation. In the context of our research, the former two examine the congruence between the normative structure of our program theory and the implemented OPEX program, respectively between the normative and the actual OPEX program environment. The latter, in contrast, seeks to provide a basis for evaluating the mechanisms by which relevant determinants influence SFB.

To construct a program theory for impacting SFB that facilitates the three aforementioned evaluation types, we draw both on existing research as well as on our empirical analysis. (H.-T. Chen, 1990) distinguishes between three approaches for constructing program theory. They are referred to as the stakeholder approach, the social science approach and the integrative approach, of which the latter combines the former two. The stakeholder approach and the integrative approach represent alternatives that

allow bringing in the viewpoints of relevant program stakeholders for theory construction. At the same time, they also bear the risk of including vested stakeholder interest as part of theory construction (H.-T. Chen, 1990). The social science approach, on the other hand, proposes to derive program theory primarily from existing literature and from empirical observations. Since the construction of our program theory is based on insights accumulated from both review of OPEX, MC and structuration literature as well as from empirical analysis, our approach can be characterized as the social science approach.

5.4.2 Framework Construction

Program theory is commonly constructed along a logical chain involving some variation¹⁷ of the five categories inputs, processes, outputs, outcomes and impact (Rogers, 2008). The resulting model is, therefore, also referred to as a logic model. In the following we structure our program theory along the categories input, measures, outputs, direct effects and impact, since these categories best reflect the characteristics of our research problems. For example, we are less interested in the planning of input resources, which may vary based on specific organizational context such as number of employees or level of organizational OPEX maturity. Further, the identified determinants of SFB (MC, MSW, MB) are more adequately captured within a category named ‘measures’, rather than ‘processes’. Based on this initial structuring of our logic model, we make the assumes relations for impacting SFB in the following explicit by embedding our empirical insights within the existing body of knowledge on OPEX research.

Input

From review of OPEX literatures, we identify organizational context, strategy, culture, and values as relevant inputs of a program theory for impacting SFB. While further dimensions of *input* may exist that could potentially make our model even more comprehensive or more granular, we set the focus on the four aforementioned input dimensions, based on the insights derived from our review of literature as well as our empirical research. First, by taking the four inputs into account as part of an integrated framework, we comprehensively address the potential key factors for influencing the means applied in OPEX programs, that have been recognized in existing literature.

¹⁷ Common variations include resources (input), activities or measures (processes), intermediate, direct or indirect outcomes respectively results (outcomes) or final outcome (impact).

Second, they are granular enough to describe relevant inputs, without distorting from the main rationale for constructing a program theory, which is to provide a simplification of reality to help “understand, predict, make decisions, and act” (Rogers, 2000, 54 f.). In the following we elaborate in more detail on the rationale for inclusion of each of the four key inputs as part of our integrated framework.

First, we include organizational context as a key input, among others, because it has been emphasized by researchers as a potential factor that influences the returns from OPEX programs (cf. chapter 2.1). While relevance for OPEX by itself would not justify consideration as key input for impacting SFB, we consider it relevant for two reasons. First, the underlying motivation for studying the phenomena of SFB as part of this research is to provide practical and theoretical guidance for increasing the effectiveness of OPEX programs. While research that studies the mechanisms, through which contextual factors affect the outcome of OPEX programs is limited, both existing OPEX and MC research suggest that it affects performance, at least partially, through behavioral mechanisms. Our empirical findings support this view by providing empirical evidence for the presence of contextual barriers in pharmaceutical manufacturing that can affect SFB and ultimately the effectiveness of OPEX programs. Informed by these insights, we thus conceptualize contextual factors as key inputs, not only for OPEX program effectiveness, but also for SFB. To make the assumed relation between contextual factors, SFB and OPEX program implementation explicit, we build upon (Shah & Ward, 2003), who establish a relation between contextual factors and OPEX practice implementation (cf. *Figure 28*). In their article, the authors study, among others, the effects of industry type, site size, site age and degree of unionization as contextual factors on OPEX implementation. Their findings suggest that contextual factors can have a significant effect on the implementation of OPEX practices. These also include practices that are related to the MC dimensions for our research, such as cross-functional work (unionization, site age) or self-directed work teams (unionization, site size, site age). In this context, the authors point out that notably site size seems to have a substantial influence across a wide mix of OPEX practices. It is further worth highlighting, that in contrast to unionization, site size and site age, the authors only study the effects of industry type on the level of OPEX practice categories, including TPM, TQM, JIT and HRM. While they do not find significant effects of industry type on people-oriented OPEX practices on category level (HRM), they find significant effects on TPM and JIT. Since the authors do not engage in further investigation into behavioral mechanisms underlying the effects of contextual factors on OPEX practice implementation, we derive from the article primarily empirical evidence for our

assumed causal relation between contextual factors and OPEX practice implementation. For example, the article does not provide further explore how site size or industry type affect behavior in ways that influence the likelihood of OPEX practice implementation. For the construction of our program theory, we therefore view the established relation as a black box, which we can further explore. To add assumed causative relations with regard to behavioral mechanisms to the general link between contextual factors and OPEX practice implementation as established by (Shah & Ward, 2003), we draw in the following on our empirical insights.

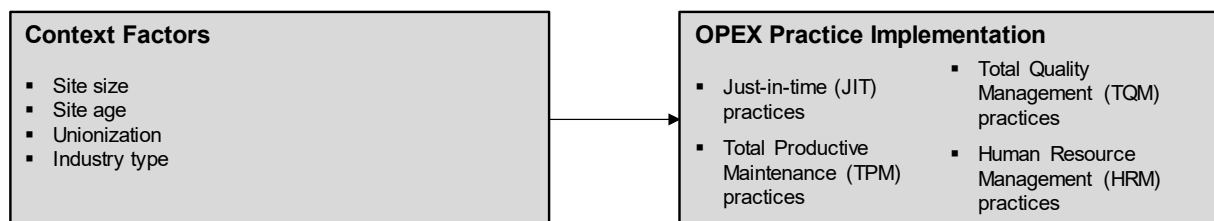


Figure 28: Influencing context factors for OPEX, adapted from (Shah & Ward, 2003)

Like with organizational context, existing OPEX research has established an explicit link between culture and OPEX practice implementation (Losonci et al., 2017). In their article, the authors distinguish three relevant types of culture (clan, hierarchical, adhocracy) along two dichotomies (control versus flexibility and internal focus versus external focus) to study the effects of culture on OPEX practice implementation (cf. Figure 29). The researchers further draw on (Martin, 1992) to distinguish three perspectives on culture, namely unitary, pluralist and anarchist perspectives. The first perspective assumes that culture is homogeneous throughout an organization, and it can be expressed by one measure of overall culture. In contrast, the second and third perspectives assume the existence of heterogeneous subcultures that are fragmented into either dominant subcultures, or into values and norms of individuals without a single dominant subculture respectively.

From a unitary perspective, the research findings suggest that two culture types impact two OPEX practice categories significantly. The clan type is associated with information OPEX practice implementation. On the other hand, the adhocracy type impacts the OPEX practice category work organization. Overall, the measure of the assumed homogeneous culture, which is an aggregation of the three culture types, is associated significantly only with information OPEX practices. Overall, the unitary perspective suggests a weak link between culture and OPEX practice implementation.

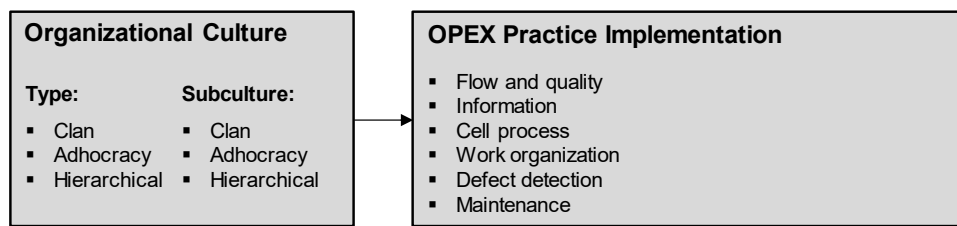


Figure 29: Relation between culture & OPEX, adapted from (Losonci et al., 2017)

When adopting a pluralist perspective, the authors find three subcultures within one case company that are named after one dominant characteristic of the culture types to distinguish them from the three culture types from the unitary perspective. The first subculture is referred to as innovation culture, referring to innovation as the dominant characteristic of the adhocracy type. The other two subcultures are participation and regulation, which relate to key characteristics of clan type respectively of hierarchy type culture. The analysis suggests that each subculture has different significant impact on the studied categories of OPEX practices. Overall, four categories were significantly affected by subcultures including information, work organization, maintenance and flow and quality.

While the study establishes a link between culture and OPEX practice implementation, the authors conclude that the relation between culture and OPEX practice implementation can also be challenged in two ways. The first one refers to an existing challenge of establishing cause-and-effect relationships between culture and OPEX practice implementation. Specifically, the authors emphasize that previous research argued that the implementation of the OPEX program blueprint TPS has changed culture in a case company, suggesting that OPEX practices impact culture. Second, the authors suggest potential challenges for making the insights derived from the research actionable for OPEX implementation, by pointing to the fact that national culture could influence affect the studied relationship.

The assumed link between culture and OPEX in existing literature, encourages us to include culture in our program theory. On the one hand, it provides empirical evidence for the hypothesized critical role those behavioral aspects play for OPEX implementation. On the other hand, it also highlights the lack of actionable guidance that existing OPEX research on organization culture provides. Research by (Bortolotti, Boscari et al., 2015) provides support for this view. As a starting point for their research, the authors identify inadequate culture as well as absence of attention to people-oriented practices as acknowledged critical success factors in OPEX literature. The authors then

study distinctive characteristics of successful OPEX adopters in terms of cultural aspects as well as implementation of both people-oriented and operations-oriented OPEX practices. With regards to the role of the former, they identify institutional collectivism, future orientation, assertiveness, humane orientation as distinctive cultural characteristics of successful OPEX adopters. In terms of people-oriented OPEX practices, they identify among others small group problem solving and training of employees as differentiating factors. Finally, their findings suggest that operations-oriented OPEX practices are essential but not differentiating, since they only differentiate successful sites when simultaneously considering people-oriented practices. While they do not correlate the different variables to each other or explore the underlying causal relations, the authors conclude that both cultural aspects and people-oriented practices should be taken into since both differentiate successful sites. The authors further conclude that future research is needed to explore how culture and people-oriented practices interact and thus affect OPEX program effectiveness. Based on the limitations of existing literature as highlighted in the two recent studies, we consider the inclusion of culture in our program theory worthwhile, even though we do not explicitly explore on the role of culture as part of our empirical research. Specifically, it can contribute to the ongoing discussion on the role of culture for OPEX in a meaningful way by making assumed causal links between culture and the determinants of SFB identified as part of this research explicit as a basis for further research.

Like culture, we consider strategy and values as key inputs without explicitly focusing on them as part of our empirical research. Strategy has been identified from a theoretical perspective as an important factor to consider as part of OPEX implementation. Yet, few OPEX research empirically investigate its role for OPEX success. A notable exception includes (Bortolotti, Danese et al., 2015). Drawing on existing OPEX literatures, the authors identify the manufacturing strategy as a key determinant of OPEX success, without which companies lack a clear roadmap for orienting OPEX activities in the right direction. They further suggest that the manufacturing strategy should be aligned with the overall business strategy and should be shared with external suppliers to facilitate working towards common goals. As part of a subsequent quantitative analysis, the authors study the relation between manufacturing strategy, OPEX practices and cumulative operational performance. The findings suggest that a distinct sequence for cumulative performance improvement exists. Based on the analysis, the authors further identify manufacturing strategy, people-oriented OPEX practices, TPM practices and supplier relationship practices as a

foundation for the effective implementation of further bundles of OPEX practices and cumulative performance. Based on the foundational role of strategy for OPEX practice implementation, the authors suggest that managers should not only share the strategy with external stakeholders, but also strive to communicate it to other functional areas internally to build an adequate organizational culture. Based on the established relations, we conclude for our program theory the importance of developing adequate manufacturing strategy, both for overall OPEX effectiveness and for affecting desired organizational behavior.

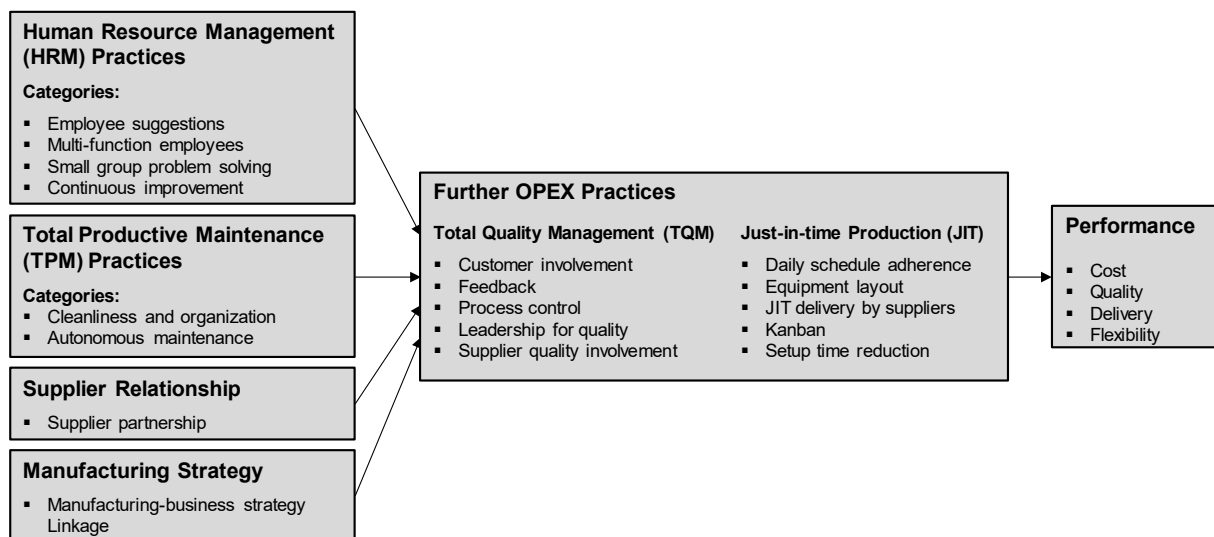


Figure 30: OPEX practices & performance, adapted from (Bortolotti, Danese et al., 2015)

Finally, values represent the last of our four key inputs. In a recent study, (van Dun et al., 2017) identify values of effective OPEX managers together with behaviors that are structured along (Yukl et al., 2002) three behavioral domains (task-orientation, relation-orientation, change-orientation). In addition, the study includes behaviors categorized as counterproductive in literature. The values and behaviors of effective managers were derived among other from literature review and were subsequently ranked based on values and behaviors of six managers deemed effective by external experts from outside the organization and their supervisor. Among the highest ranked values within the analyzed sample were honesty, responsibility, teamwork and participation, candor, and continuous improvement, all of which are according to the authors “indicative of self-transcendence and openness to change” (p.174). As a main finding, the authors thus suggest that effective hold values of self-transcendence and openness to change. Of the five values, participation and teamwork as well as continuous

improvement were identified by the existing body of knowledge as potentially critical values. In terms of future OPEX research, the authors conclude that a merge “with other ‘pockets’ of the more ‘softer’ leadership and change management literature is likely to further enhance both research knowledge and practitioner competency” (p. 181) to support OPEX. The authors close by making five propositions for effective OPEX managers one of which suggests that values of self-transcendence and openness to change are positively associated with relations-oriented behaviors.

Values		Management Behaviors	
▪ Honesty ▪ Participation and teamwork ▪ Responsibility ▪ Persistence ▪ Achievement-orientation ▪ Trust in people ▪ Open minded ▪ Respect for people ▪ Continuous improvement ▪ Information sharing and analysis ▪ Equality ▪ Integrity	▪ High quality performance ▪ Potential of ordinary employees ▪ Freedom of choice ▪ Humility ▪ Self-reflection ▪ Justice ▪ Helpfulness ▪ Courage ▪ Creativity ▪ Customer focus ▪ Constructive feedback ▪ Innovation	Task-oriented behavior: ▪ Structuring the conversation ▪ Informing ▪ Task monitoring ▪ Delegating ▪ Structuring followers' time	Change-oriented behavior: ▪ Visioning ▪ Asking for ideas
		Relations-oriented behavior: ▪ Active listening ▪ Agreeing ▪ Encouraging - enthusing ▪ Providing positive feedback ▪ Encouraging - cooperating ▪ Socializing ▪ Showing personal interest	Counterproductive behavior ▪ Showing disinterest ▪ Disagreeing ▪ Enforcing ▪ Providing negative feedback ▪ Defending one's own position

Figure 31: Values & behaviors of effective OPEX managers, adapted from (van Dun et al., 2017)

In terms of behaviors, the authors suggest that in order to encourage employees to express their reflective thoughts and ideas for CI, OPEX managers should “agree more often with their follower's suggestions in an appreciative manner. Furthermore, they should engage less in command-and control type of behaviors; welcome change efforts; and build close human relations at work.” (p. 183). They further suggest that effective managers engage significantly more in positive relations-oriented behaviors, such as agreeing or active listening. Contrasting the importance that our case companies attach to the MSW component process confirmation, the study further suggests that effective managers engage significantly less in task monitoring from the task-oriented domain. The study derived the effective values and behaviors from comparing data of the deemed effective OPEX managers with data of effective non-OPEX managers from a similar study. In These non-OPEX were neither directly involved in OPEX programs, nor did their sites implement OPEX at the time of the study. The findings of the authors could therefore also be interpreted as differences between OPEX managers and other managers, as both compared groups were comprised of managers deemed effective. For the context of our research, we conclude that an established link between values and behaviors of managers exist in OPEX literature, which we can draw on to assume a relation between values and other components of our program theory.

After identifying relevant *input* determinants of SFB, we assume explicit relations among them based on the existing literature. By definition, the identified key inputs all affect the *measures*. Accordingly, we assume an effect of each *input* on the *measures*, which we will introduce in the following section. Drawing on (Shah & Ward, 2003), we further assume an effect of contextual factors on each of the other three key inputs. As we are not aware of research on OPEX programs establishing an explicit link between contextual factors and strategy, we draw on the broader operations research field (Ward & Duray, 2000) and assume that context plays also a substantial role in strategy formation for OPEX programs. Finally, we assume on the one hand an effect of organizational culture on values. As (van Dun et al., 2017) point out, (Yukl, 2010) suggests that “values are likely to be internalized by managers who grow up in a particular culture, and these values will influence their attitudes and behavior in ways that may not be conscious.” (p. 431). Based on the potential bidirectional relation between culture and OPEX practice implementation, we further conceptualize the relations between culture and values as well as between values and *measures* as bidirectional.

Measures

MC and MSW depict the *measures* of our program theory, both of which represent depict structural means for affecting SFB respectively MB (cf. chapter 5.2.5). Since MSW formalizes the intended MBs, it covers the same three MB dimensions, namely *communication*, *power*, and *sanction*. MC, on the other hand, comprises the six identified MC dimensions. Informed by our quantitative analysis as well as (Nielsen et al., 2018), we assume the dimensions of MC to be highly interrelated.

First, we draw on the concept of *input*, *process* and *output* control to assume unidirectional links between the respective MC control dimensions (cf. *Figure 32*). Since all six dimensions can affect SFB along subsequent phases, we assume that all *input* controls can affect *process* controls, which in turn can affect *output* controls. Additionally, we identify a logical sequence among the dimensions of *input* controls, since *employee empowerment* can be influenced by *training* in terms of capability building, as well as the fact that effective *training* should support set goals. For *visualization* and *standardized work*, on the other hand, we do not assume a logical sequence, as indicated by the lack of a directional relation.

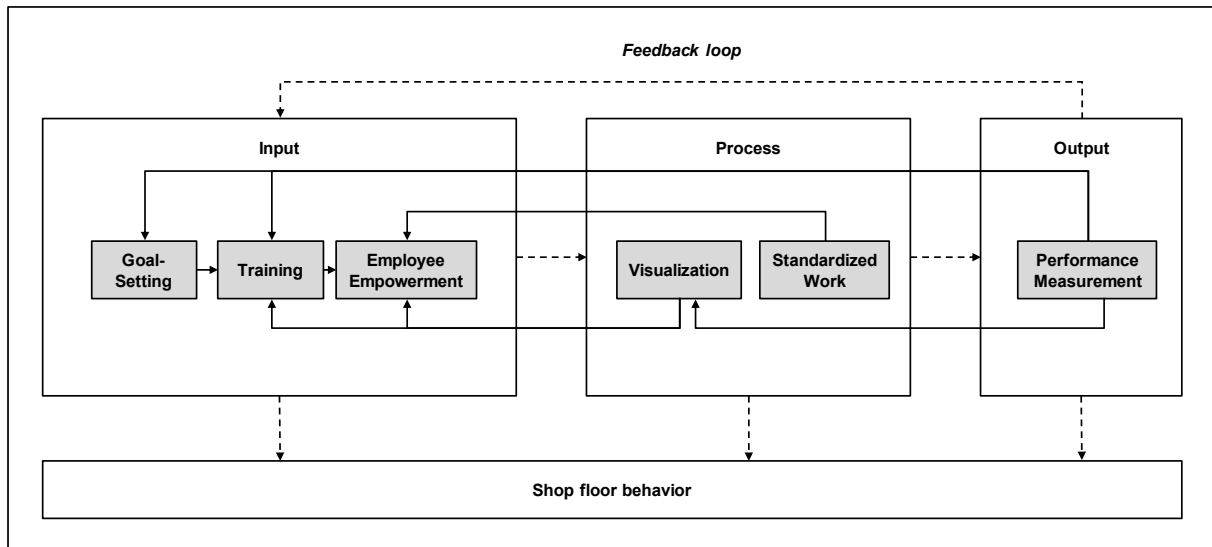


Figure 32: Assumed interrelatedness between relevant Management Control dimensions

Finally, we assume reinforcing loops between the MC dimensions, based on the identified intended and unintended effects of MC. Starting with output control, we assume that information from *performance measurement* can be used to iterate *goal setting* or to identify focus topics for *training*. We further assume that it can provide input for *visualization*, which can in turn affect *training* and *employee empowerment*. Finally, the latter can be affected by *standardized work*, as illustrated by the unintended consequences of SOPs.

Output

By the same token by which we conceptualize MSW and MC as *measures* of our program theory, we view MB as one of two categories of *output*. It is directly influenced by MSW and comprises the three interrelated MB dimensions *communication*, *power* and *sanction*. Drawing on our double loop model, we assume a direct effect of MSW on MB, as well as an indirect effect of MB on MSW. To illustrate, based on our observation MSW is used in the studied pharmaceutical companies to guide MB, while MB only influences MSW indirectly in the form of intended effects on SFB, and only during the design phase of the OPEX programs.

Drawing on (Giddens, 1979), we further consider interpretative schemes, norms and facilities as the second category of *output*. They represent assumed direct effects of MC and are interrelated, likewise the three MB dimensions. Based on our empirical study, we further distinguish between intended and unintended consequences for both MSW and MC. Finally, both are assumed to be interrelated, to account for concept of *duality of structure* as well as for the observed interactions between MC, MB and ultimately SFB as part of our empirical research.

To provide further support for our assumed relation between MB and SFB, we build upon existing research by (Camuffo & Gerli, 2018). To explain why OPEX programs may succeed or fail, the authors highlight the importance of guiding MB for OPEX by deriving a set of MB associated with OPEX programs from literature (cf. *Figure 33*). Following (Marodin & Saurin, 2015), they further adopt of a situational perspective suggesting that OPEX programs need to be not only internally but also externally aligned. Based on a subsequent quantitative analysis, the authors derive six MBs that are associated with companies with higher levels of OPEX practice adoption in a specific context, including versatility, organizational focus, standards development supportiveness, capability building and performance evaluation. Based on these findings, the authors propose that, from a situational perspective, the sets of differentiating MBs will likely vary depending on organizational environment or industry, strategy, culture, size, adoption of OPEX practices, or maturity of OPEX adoption. Thus, the authors suggest that subsets of adequate MBs should be derived depending on organizational contexts. Furthermore, they conclude that “the identification of such subsets of behaviors and their alignment with the firm’s strategy, culture, and external environment, is a key task for the top management of any company” for a successful OPEX implementation (p. 17). Finally, the authors suggest in the discussion section that by identifying MBs, which may support sustained OPEX practice adoption, the study provides “an interface among organizational design, management control, and human resource management” (p. 18), without any further reference to organizational design or management control.

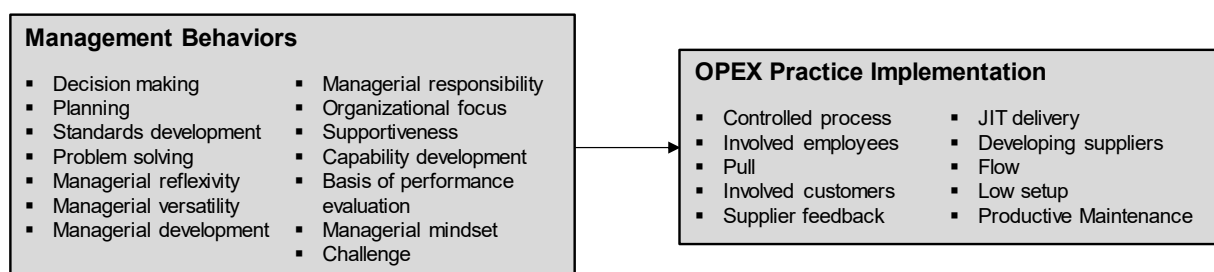


Figure 33: Impact of management behavior on OPEX, adapted from (Camuffo & Gerli, 2018)

The interplay between MB, context and OPEX implementation is also implicitly studied by (Tortorella et al., 2018) based on an analysis of responses from leaders of Brazilian companies. The authors suggest that existing research on the role of MB in OPEX programs focuses too little on understanding the complex contexts in which leadership takes place. Among others, the authors study moderating effects of team size

and leader's age on the relation between task-oriented or behavior-oriented leadership styles and OPEX practice implementation (cf. *Figure 34*). Interestingly, in contrast to (van Dun et al., 2017), the study suggests that higher levels of OPEX implementation are associated with task-oriented management styles, rather than relation-oriented styles. The authors further propose that the effects of relation-oriented styles are contingent upon team size. Finally, the study suggests that increases in team size and leaders age are negatively associated with OPEX practice implementation.

Similarly to (Camuffo & Gerli, 2018), the authors consider adequate MB for OPEX program implementation as a contingency issue. Among others, the findings suggest that OPEX implementation is expected to require different MBs depending on the context in which leaders find themselves in. Accordingly, MB should be adjusted to organizational circumstance. Since behavioral change is expected to take long periods of time, the authors further highlight the importance of designing OPEX programs in a way that stimulates adequate MB in a sustained way.

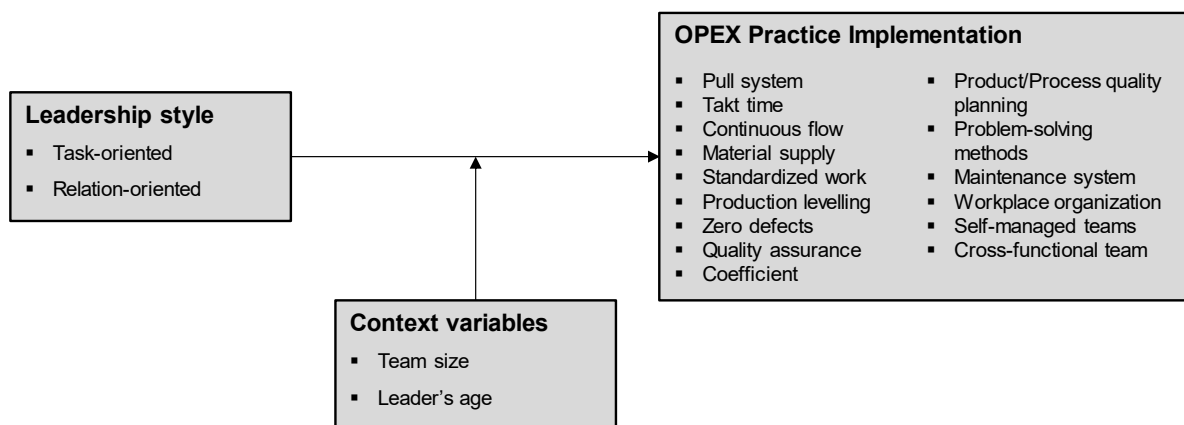


Figure 34: Relation between leadership, context & OPEX, adapted from (Tortorella et al., 2018)

In conclusion, both articles highlight the importance of guiding MB based on structural aspects of OPEX programs, thereby supporting our conceptualization of MB as an *output* of MSW. The articles further suggest a contingency of adequate MB on organizational circumstance, which we account for on the one hand by our *input* determinants. On the other hand, the studies emphasize that successful management approaches may not be transferrable from one organization to another but should instead be evaluated for each specific organizational context. Since a variety of factors can influence the context of MB, including OPEX practice adoption, environment or culture, our program theory can help evaluate management approaches for different contingencies.

Direct effects

To the best of our knowledge, the existing body of OPEX knowledge does not comprehensively study mindset-related determinants of adequate SFB, apart from values, that can be influenced by managers. To still assume mindset-related antecedents of SFB as *direct effects* of our program theory, we draw on (Emiliani, 1998). The study depicts one of few studies that elaborates on potential antecedents of OPEX behavior, without focusing exclusively on the behavior of managers. The author identifies, among others, OPEX-behaviors and non-OPEX behaviors that, according to the author, are associated with waste avoidance respectively with waste. Examples of OPEX behaviors include consistency, listening, discipline or reflection. Among others, examples of non-OPEX behaviors include ambiguity, uncertainty, criticism, inaction or self-imposed barriers. The author further proposes consequences of non-OPEX behaviors, for example, unclear expectation, lack of improvement suggestions, slow response to changing conditions, employee turnover, or blind obedience. Finally, the author proposes the following set of mental conditions of ideal OPEX personnel, which we can build upon, even though it may not be entirely influenceable by managers. These comprise:

- Self-discipline
- Challenging activities matched to personal skill
- Focused attention
- Clear goals
- Immediate feedback
- Freedom from external concerns
- Sense of control
- Loss of self-consciousness
- Altered sense of time

Informed by (Emiliani, 1998) as well as by the empirically derived behavioral implications of MC and MSW, we derive four categories of relevant SFB antecedents for our research context that represent the *direct effects* of our program theory. First, *discipline* accounts for the importance of individual effort and perseverance for achieving sustained organizational changes. MBs identified as part of this research that can affect *discipline* include among others *make expectations transparent* (MB02) or *adhere to MSW* (MB07). Both can support *discipline* by communicating what is expected, while demonstrating that management is equally committed to demand adherence to standards. As a second antecedent we identify *focused attention*. It is not only in line with (Emiliani, 1998) and our empirical findings, but also corresponds well

to (Ocasio & Wohlgezogen, 2010), who highlight the importance of attention for in the context of MC.). Notable examples of MBs to influence *focused attention* include *showcase the desired behaviors* (MB06), *routinely ask for SOP reference* (MB10) or *routinely ask for data* (MB14). To illustrate, the latter two were intended in our case companies among others to direct the attention of shop floor personnel towards both SOPs and data, as a basis for identifying improvements and making decisions. The third category depicts *enablement*, which accounts for a variety of previously outlined aspects, including (Emiliani, 1998) match of activities to personal skills, clear goals, immediate feedback and sense of control, or the importance capability building, timely actions or role modeling as emphasized as part of our empirical research. Exemplary means for managers to influence this antecedent include *show equal commitment to OPEX and to compliance* (MB15), *act with immediate responsiveness* (MB08), or *encourage calculated risk taking and learning from failure* (MB16). All these MBs can be viewed as forms of management support, that can enable shop floor personnel to contribute to OPEX in the pharmaceutical manufacturing environment. Finally, we add *motivation* as a fourth category of SFB antecedents, which is not considered by (Emiliani, 1998). Based on motivation we seek to account for the identified barriers and unintended consequences causing worker frustration and lack of active participation in the process of CI. Potentially supportive MBs include *consistently explain the reason behind OPEX program elements* (MB03), *create a sense of urgency* (MB12) or *create enthusiasm based on ambitious targets* (MB13).

Impact

To complete the construction of our program theory for impacting SFB, we relate the *impact* to the other four logical chain categories. All previously outlined determinants ultimately have a direct or indirect effect on SFB. As elaborated above, SFB is directly affected by the four mental antecedents, which in turn are indirectly affected by MC and MSW. Following (van Dun et al., 2017), SFB can further potentially be directly influenced by the shop floor personnel's individual values as well as by organization values, which we assume can interfere with individual's mindset.

Since the purpose our program theory is ultimately to provide guidance for impacting SFB in a way that increases operational performance, we include a link between SFB and operational performance as part of our program theory. Drawing on existing OPEX research and supported by our quantitative analysis, we further assume a direct relation between SFB, operations-oriented OPEX practices and performance.

While few OPEX research exists that empirically studies the individual impact of operations-oriented and people-oriented OPEX program components on operational performance, we can further draw on (Hadid & Mansouri, 2014) to assume explicit links between all three components. (Hadid & Mansouri, 2014) study the relation between technical and so-called supportive OPEX practices on operational performance and find direct effects of both on operational performance (cf. *Figure 35*).

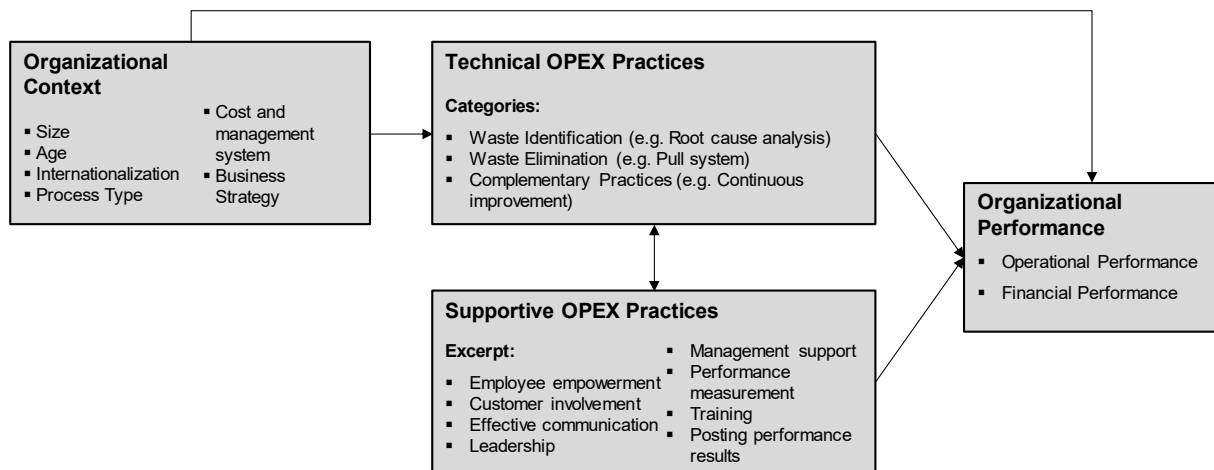


Figure 35: Relation between context, technical and supportive OPEX practices and performance, adapted from (Hadid & Mansouri, 2014)

Like our research, the authors find an interrelation between technical and the people-oriented supportive OPEX practices. Informed by our empirical research we follow this conceptualization and assume, in addition to the indirect effects of MSW and MC on OPEX practices, an effect of operations-oriented OPEX practices on MC. Since operational performance represents the input for the MC dimensions *performance measurement*, we further assume a feedback relation between operational performance on MC. Finally, we draw on our empirical findings that suggests that intended SFB plays a central role in the design of MSW as part of the studied OPEX programs. We therefore assume a relation between SFB and MSW. The resulting logic model for impacting SFB is presented in *Figure 36*.

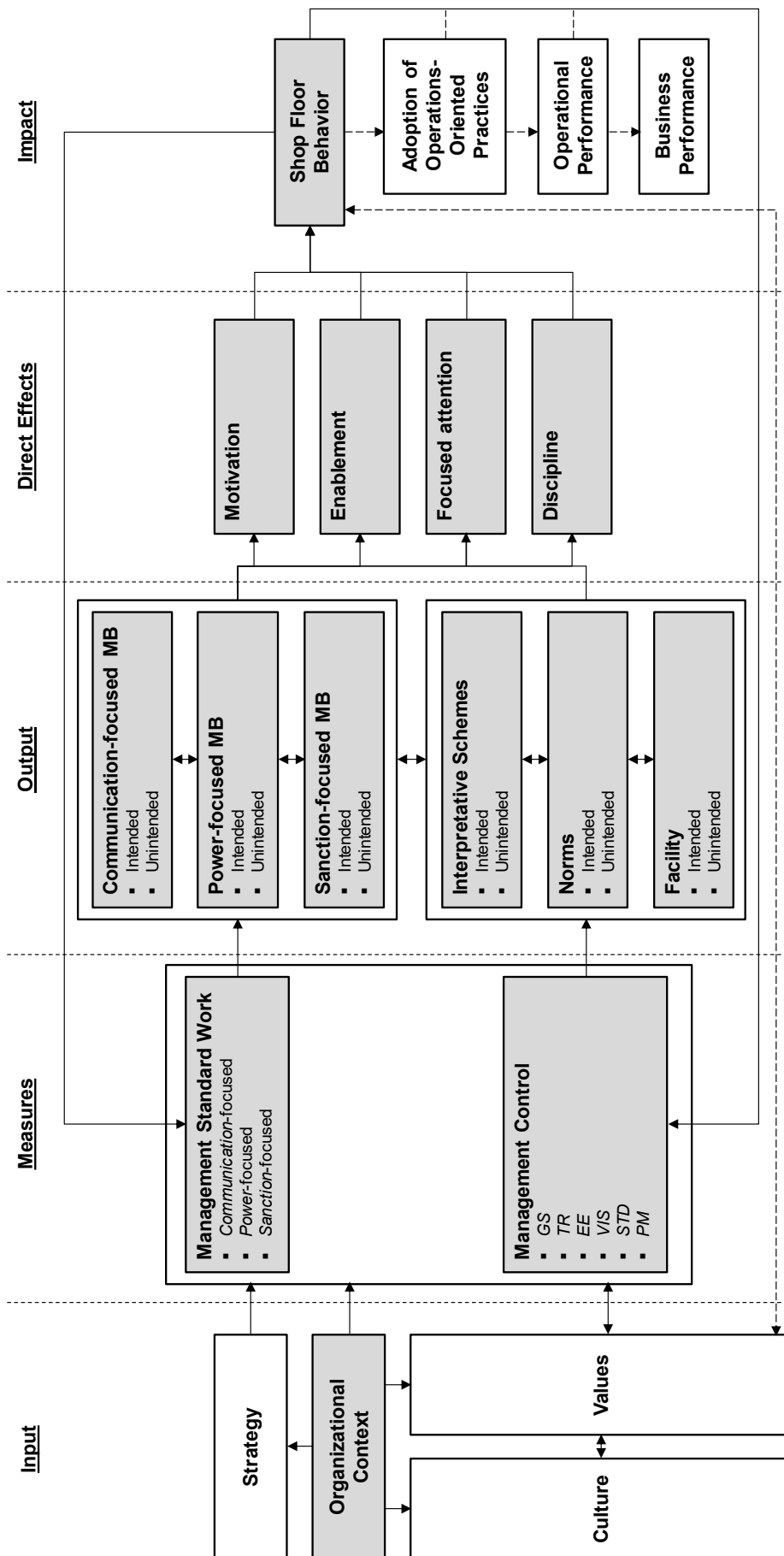


Figure 36: Logic Model for Impacting Shop Floor Behavior

5.5 Validation of Empirical Findings

The empirical findings from this research are validated based on research group work and discussions with industry contacts that were established as part of working in the Operational Excellence team of the ITEM-HSG.

Discussion in research group

To validate the identified barriers, the research group was asked to review and evaluate their criticality. All eight barriers were confirmed by the representatives from all companies as potentially important obstacles for impacting shop floor behavior in desired ways for OPEX. In addition, the research group was asked to identify further relevant barriers that may not have been covered, which did not bring forward additional overarching contextual barriers. Yet, it provided several variants of the identified barriers, which inspired name change for two barriers. A category that was previously coined *limitation to experimental learning* was identified as a subcategory of the broader barrier *high effort to execute changes*. Similarly, *shallow empowerment* was pivoted into a broader category named *lack of sense of urgency*. The validation in the group also provided several subcategories of the already identified barriers, which validated their relevance indirectly. For example, *lack of service orientation of quality organization* was highlighted by one participant as a critical barrier, which can be viewed as a facet of the identified broader category *separation of quality from OPEX*.

Like the barriers, the management behaviors were discussed and validated in the research group based on review by the group with subsequent check for any missing relevant management behaviors. The group review resulted in none of the identified behaviors being excluded as unsupportive. The research group was then asked to split up in three groups to identify in their own words the five most effective management behaviors for impacting shop floor behavior in OPEX programs. Each group defined management behaviors as part of their respective top three that are associated with the three type management behavior types (*communication, power, sanction*), underlining the relevance of all three categories for OPEX practitioners in pharmaceutical manufacturing. All behaviors were further represented by the management behaviors identified as part of this research.

Finally, the preliminary framework for impacting shop floor behavior was presented to the research group and validated. The adequacy of the assumed relations between its building blocks was critically reflected and validated by the group against the experience of the research group participants from implementing OPEX programs in pharmaceutical manufacturing. The framework was considered an adequate

representation of the complex task of impacting shop floor behavior. Further, based on the presented framework the relevance of adopting an integrated perspective on human behavior management that takes contextual, structural and behavioral aspects into account in the context of OPEX programs was supported by the group.

Discussion with advisors to pharmaceutical industry

The significance of the identified barriers was additionally validated based on interviews with two OPEX and quality subject matter experts that work as advisors in different fields of the pharmaceutical industry. All barriers were identified as valid and of high relevance in pharmaceutical manufacturing.

The first interviewee works as vice president regulatory affairs at one of the leading pharmaceutical associations and is well experienced with the regulatory dialogue inside and outside the U.S.. Over the course of the past 20 years, the interviewee has developed great expertise in developing technical and scientific consensus expertise documents for pharmaceutical manufacturing. One focus of the current role is on writing regulatory comments and opinions for new guidelines and regulations, in close collaboration with industry experts. Working with a variety of pharmaceutical companies across the globe, the interviewee has gained first-hand insights into the process of global harmonization of pharmaceutical production requirements, as well as manufacturing and quality assurance practices.

The second interviewee has recently started in a new role as principle at a small consulting business that advises biotechnology companies on how to enhance their manufacturing capabilities. Prior to starting in the current role, the interviewee worked in a global role within the analytical development group of a large global pharmaceutical manufacturer. In this capacity the interviewee had the task of providing technical support for different product lines, including eight biologics manufacturing sites across the production network. Among others, this included leading global analytical teams from the company's global technology and engineering division. As part of this role, the interviewee operated at a higher oversight level, which involved making sure that products are produced to specifications, minimizing risks of stock outs, or ensuring resilience of the supply chain. As part of these tasks, the interviewee aimed to determine how well relevant processes are operating according to standards to ensure that they do not cause compliance or other issues.

Discussion as part of industry projects

Parts of the findings from this research were also validated as part of two industry projects that focused on the role of the management system for OPEX. The findings were discussed with subject matter experts from two global pharmaceutical manufacturers (PharmaCo A and PharmaCo H).

At PharmaCo A, the identified barriers and the quantitative results were used to critically reflect the latest iteration of the company's OPEX management system as part of its pilot phase. The empirical findings were discussed, first, with the company's Global Head of OPEX to critically reflect the results. Both the barriers and the quantitative results corresponded well to his experiences made at different sites of the company. The findings were further viewed as confirmation of the company's recent shift towards a stronger focus on management routines and leadership behavior. The results were subsequently presented to a global steering committee of the company to inform the further roll-out of the management system iteration to further sites.

At PharmaCo H, parts of the quantitative findings were discussed part of a work package, intended to provide empirical guidance during the finalization phase of the company's new OPEX program. As part of this check, the findings were discussed with both the Global Director OPEX and a local OPEX Director. The validation was part of a broader consistency check of the company's OPEX program components, covering all elements of the underlying theoretical model of the quantitative analysis (OPEX management system, OPEX operating system and operational performance). The check showed that the new OPEX program covered all MC dimensions that were studied as part of the quantitative analysis. The analysis of the program elements revealed, however, that the company had not yet defined the *goal setting* approach for achieving OPEX. In addition, it had not defined intended management behaviors, even though they were recognized as a center piece of the future OPEX program. Overall, the discussion of the quantitative results along the company's new OPEX program provided, on the one hand, support for the central role that all six MC dimensions play for a successful OPEX implementation. On the other hand, it provided empirical evidence that even the most recent OPEX programs of leading global pharmaceutical manufacturers may not account for counterproductive effects of *goal setting* or *standardized work* specifically, and of MC more generally.

6 Contributions to Theory and Practice

This research set out to provide practical and theoretical guidance for impacting shop floor behavior in the context of pharmaceutical OPEX programs. In the following, the managerial implications as well as the contributions from addressing the research problem along an iterative learning process are outlined. This chapter closes by outlining the limitations of this dissertation together with a research outlook.

6.1 Managerial Implications

This dissertation enriches the preliminary theoretical understanding that underlies the developed research model, based on empirical data that is used to answer the following research question:

How can managers impact shop floor behavior in the context of pharmaceutical Operational Excellence programs?

The empirical findings show that managers can influence shop floor behavior in the context of pharmaceutical OPEX programs in various ways. These include both their own behavior and MC. Moreover, several managerial implications can be derived from the empirical findings, which will be outlined in the following.

Contextual peculiarities matter

Contextual peculiarities can affect the social OPEX subsystem in different ways, which should be accounted for by practitioners. On the one hand, contextual peculiarities can limit the scope of feasible intended behaviors, as shown by the identified barriers from the pharmaceutical manufacturing environment. More generalized, these suggest that practitioners could benefit from taking characteristics of the manufacturing processes (e.g. *knowledge intense value creation*), the cross-functional interplay between different departments (e.g. *lack of service orientation in quality organization*), or industry type (e.g. discrete versus process industry) into account. In addition, the regulatory context (e.g. regulated versus not-regulated environment) depicts a critical contextual factor that plays into many of the identified barriers. On the other hand, the empirically derived unintended MC consequences suggest that the behavioral implications of the relevant MC dimensions are, in parts, context dependent. Both the contextual barriers and the

unintended consequences of MC, therefore, highlight the influence that contextual peculiarities can have on human behavior management in the context of pharmaceutical OPEX programs.

To account for contextual peculiarities, managers should therefore ensure that the applied means for guiding behavior are externally consistent. For this purpose, they should invest enough effort into understanding the behavioral implications of contextual peculiarities for the means applied to influence shop floor behavior. This can include, critically reflecting applied management behaviors and MC dimensions, based on the identified barriers for OPEX shop floor behavior.

Integration of means for impacting behavior by effect rather than by category

In order to support MC with suitable management behaviors, practitioners should focus on the effects of both MC and management behaviors. To illustrate, the identified supportive management behaviors are typically not exclusively associated with one MC dimensions, as shown by the empirical findings. As outlined in this research, each MC dimensions has several intended effects and further affects several behavioral mechanisms, that range from motivation to discipline. The identified management behaviors can therefore support different MC dimensions, depending on the intended or unintended MC effects that can be strengthened or mitigated by a respective management behavior. Focusing on the broad categories, such as MC dimensions, will therefore likely not contribute adequately to an effective integration of MC and management behaviors. Practitioners can instead follow the approach adopted in this research and can link management behavior and MC based on their effects.

Consideration of unintended MC effects to avoid OPEX programs failure

The empirical findings suggest that unintended effects of MC should receive more management attention in the context of pharmaceutical OPEX programs. As outlined in this research, MC can influence shop floor behavior in both advantageous and disadvantageous ways for OPEX. Effectively impacting shop floor behavior for OPEX, therefore, requires considering both of these MC effects, in order to obtain desired effects, while avoiding unintended ones. Yet, unintended effects of MC play only a minor role, if at all, in all studied pharmaceutical OPEX programs.

This research suggests that impacting shop floor behavior in the context of pharmaceutical OPEX programs demands a lot from managers. As depicted in the constructed framework for impacting shop floor behavior, different determinants affect shop floor behavior through complex behavioral implications. MC, contextual barriers, and behaviors of managers all have behavioral implications that can affect shop floor

behavior in different ways that can be interrelated. Focusing primarily on intended effects of MC to the neglect of unintended ones that can result from interrelations with the other determinants can therefore cause various conflicts that can deviate the OPEX program from its intended course. The observed neglect of unintended consequences can thus be viewed as a potential reason why OPEX programs are frequently revised or even fail.

Importance of internal consistency

Impacting shop floor behavior should be considered a complex social intervention that requires comprehensive and integrated organizational efforts. In addition to ensuring consistency of the means applied to impact shop floor behavior with contextual factors, managers should strive for internal consistency of the applied means. The developed framework for impacting shop floor behavior implies three potential sources of internal inconsistency that should be accounted for to achieve intended effects, while avoiding unintended ones. On the one hand, they should be mindful of the interrelations between relevant MC dimensions. Based on this research, these can involve both unidirectional relationships and reinforcing loops. Managers should further seek to ensure that the MC implications, in terms of interpretative schemes, norms and facility, are consistent with the applied management behaviors. Finally, from a structuration perspective, they should be wary of potential conflicts that may arise from inconsistencies between structural and behavioral aspects, in terms of the interrelated MB dimensions, on the one hand, and the likewise interrelated interpretative schemes, norms and facility, on the other hand.

An iterative approach can help manage the complexity of impacting behavior

To address these issues, managers should adopt an iterative approach to impacting shop floor behavior with OPEX programs. According to (H.-T. Chen, 1990), program theory impact evaluation involves assessing a programs impact in terms of intended and unintended effects after it has been implemented in the field. Since the behavioral effects of OPEX programs that become visible only after program implementation may turn out to be unintended, practitioners could benefit from following an iterative approach during OPEX program implementation. While such an approach may offer improvement potential for any program theory, it can be mission critical for impacting shop floor behavior with OPEX programs, since each of the six MC dimensions can represent a potential source of unintended consequences that may require subsequent iterations.

Based on the constructed program theory, seven distinct steps that could help managers impact SFB more effectively can be abstracted in the form of a simplified standard procedure (cf. *Figure 37*). First, managers should identify contextual peculiarities for impacting SFB with OPEX programs to account for contingency factors that may affect SFB. In a second phase, managers should derive intended effects and potential unintended effects for impacting SFB, based on the identified contextual peculiarities. Third, they should set the focus on a limited number of intended effects and potential unintended effects to limit the complexity of the planned intervention. In addition, managers should derive goals or outcomes to be pursued, as a basis for focusing program resources and activities for impacting SFB adequately. After these three steps, managers should tailor MSW and the MC system to accommodate the achievement of these goals, while minimizing the potential for unintended effects. In the fifth step, managers should implement the derived changes, followed by evaluating the achievement of the intended effects and identifying the actual unintended effects in the sixth step. Finally, managers should re-iterate the steps from step three onwards as a mean to address the uncertainty of outcome that is assumed from complex social interventions.

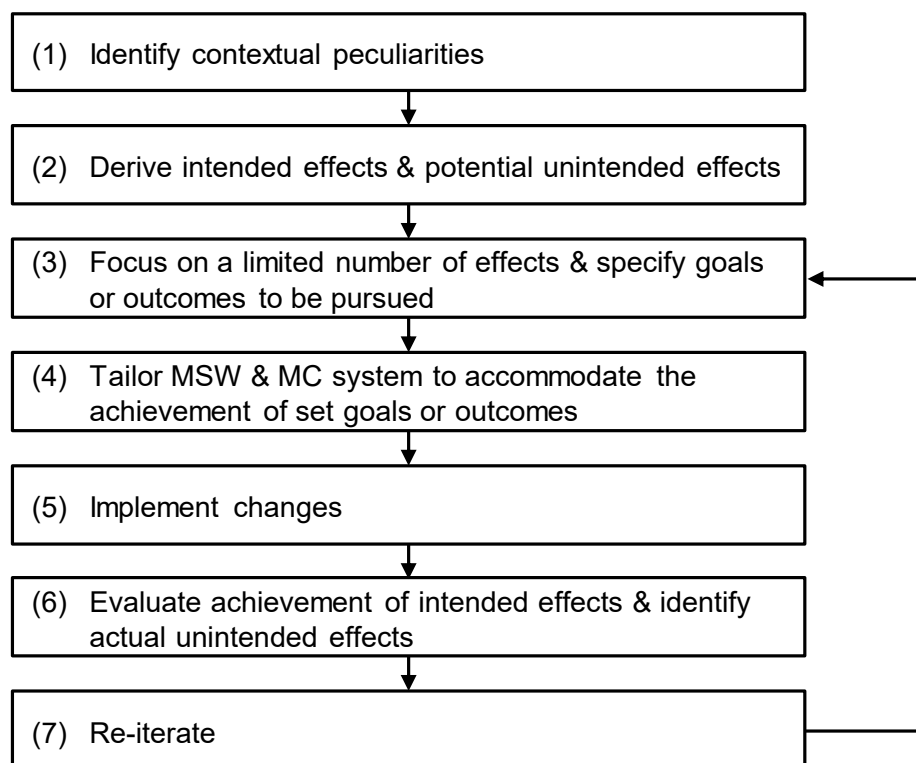


Figure 37: Proposed simplified standard procedure for impacting SFB

6.2 Theoretical Contribution

Following the understanding of (Ulrich, 1982, 1984) of application-oriented research, this research aims at generating practical and theoretical knowledge to inform a science-driven management of shop floor behavior for OPEX. In this context, this dissertation contributes to existing OPEX research in several ways that will be outlined in the following.

First, this research contributes to contextual OPEX research and thus addresses calls for situated approaches that take the context of managing OPEX implementation into account (Netland, 2016). As outlined as part of this research, existing OPEX research predominately studies the effect of contextual factors on the culture or on the OPEX operating system, to the neglect of other aspects of the social OPEX subsystem, such as MC or management behavior. By identifying barriers from the pharmaceutical manufacturing environment, this research provides empirical evidence for the influence that contextual factors can have for impacting behavior in the context of OPEX programs. This contributes to extending existing knowledge, which predominately assumes universal benefits from applying OPEX practices (Liker, 2004; Ohno, 1988; Womack et al., 1990).

Next, this research contributes to a better understanding of the role of MC for OPEX. On the one hand, it identifies relevant MC dimension in the context of OPEX programs to help practitioners influence shop floor behavior comprehensively for OPEX. By doing so, it contributes to making the broad body of knowledge from MC literature available for OPEX research that has primarily been discussed in the context of strategy formulation and implementation. On the other hand, it shows that many control mechanisms from MC literature are insufficiently covered in OPEX literature including, planning and budgeting, reporting, shared values, rewards, authority, reviews, work specialization, formalization, or centralization. Existing OPEX literature on people-oriented OPEX practices therefore neglects many potentially relevant control mechanisms that have already been identified in MC literature as critical means for affecting organizational behavior.

Third, this dissertation contributes to empirical research on the role of the management system for OPEX implementation. Specifically, it contributes to deepening the understanding of the role of MC for OPEX implementation that still only few studies have empirically examined, by quantitatively studying the effects of individual MC dimensions (cf. chapter 2.2). OPEX researchers could build upon the identified moderating effects of MC to distinguish different types of people-oriented OPEX practices, such as dimensions of MC, and to separately study their effects.

Finally, this dissertation contributes to deepening the understanding of the complex behavioral implications as part of OPEX programs, which has been identified as a practical challenge for OPEX implementation in the existing literature. First, it provides empirically derived evidence for the complex interplay between the identified determinants by studying unintended consequences, supportive managerial behaviors, standard management interactions, as well as contextual barriers for impacting shop floor behavior. In addition, it contributes to enhanced theoretical and practical guidance for impacting shop floor behavior with OPEX programs, by developing a framework that conceptualizes the complex social interactions based on the structuration theory. Researchers and practitioners can build upon the constructed framework to validate it and to adjust it for use in other contexts, including other industries.

6.3 Practical Contribution

This dissertation makes three main practical contributions that provide practical guidance for addressing the studied research problem.

First, this dissertation extends the existing knowledge on human behavior management in OPEX literature by developing a framework for impacting behavior with pharmaceutical OPEX programs from both desk research and empirical research. The framework makes the complex interrelations between relevant determinants explicit. As outlined in this thesis, impacting shop floor behavior is viewed as a complex social intervention. While it is also recognized as such by practitioners of the studied companies, interrelations between the identified key determinants are mostly not conceptualized in practice. As a result, assumed cause-and-effect relations remain implicit. Practitioners therefore primarily rely on their experience as well as on vague principles to manage intangible cause-and-effect-relations. By drawing on the structuration theory, on the one hand, and on MC literature on the other hand, this research contributes to making cause-and-effect-relations that are related to the practical problem tangible. On the one hand, it provides a conceptualization of key determinants that practitioners can draw on. On the other hand, it makes the assumed relations between the determinants explicit, in terms of the constructed program theory. Practitioners and researchers, including those from other industries, can therefore build upon this framework to help manage OPEX more effectively.

This research further provides practical guidance for impacting behavior, by conceptualizing MC as a distinct subset of OPEX practices that can be utilized to influence shop floor behavior in pharmaceutical OPEX programs and by operationalizing it. In addition, it identifies contextual barriers, unintended

consequences of MC, as well as supportive management behaviors that practitioners can build upon to adjust the constructed framework for use in other contexts, including other industries.

Finally, the findings can help practitioners impact shop floor behavior in ways that satisfy the behavioral priorities of both compliance and OPEX. Compliance can be viewed as one facet of the intended OPEX behavior, since it is associated with adherence to standards as an intended effect. This research suggests that practitioners can apply different means to support compliance, while mitigating or eliminating potential counterproductive effects for OPEX. Specifically, it identifies the MC dimensions *standardized work* and *goal setting* as well as several management behaviors as means for facilitating adherence to standards. On the other hand, it identifies unintended consequences of said MC dimensions that can have counterproductive effects for OPEX. To facilitate both OPEX and compliance, practitioners can therefore draw on the identified supportive behaviors, to maximize compliance while avoiding unintended consequences of the MC dimensions. As a result, it contributes to satisfying the behavioral priorities of both OPEX and compliance in the regulated pharmaceutical manufacturing environment, which has been identified as a non-trivial task in practice.

6.4 Limitation and Outlook

The mixed-method research approach combines different sources of empirical data to generate comprehensive knowledge on the studied phenomenon. Future research can build upon this dissertation to further advance the study of human behavior management in the context of OPEX programs. Yet, this dissertation also has several limitations that can affect the generalizability of the findings. In the following, first, the limitations of this research are outlined. Subsequently, an outlook on future research is provided.

Limitations

First, only OPEX and quality executives contributed to the identification of relevant barriers and management behaviors as part of the qualitative research. Thus, this research does not incorporate the perspective of shop floor personnel, which could provide additional insights into barriers and the effects of MC and management behaviors that may be hidden from a management perspective. Meanwhile, the exchange with subject matter experts on executive level over a period of three years makes a significant contribution to this research. Among others, it allows incorporating the rich experience of mostly senior executives, which can be viewed as invaluable, given that both OPEX literature and MC literature emphasize complex cause-and-effects

relationships in social systems as potential research challenges. However, it also incorporates their potential biases from implementing OPEX from a management perspective, in terms of successful practices or norms. The adopted management perspective can therefore be viewed as both a potential success factor and a potential limitation.

Next, the data that is used for the quantitative analysis is itself limited by the available OPEX BM dataset. One possible limitation is that the set of available and potentially relevant control variables is limited. For example, it does not allow controlling for OPEX experience of a plant, for instance in terms of number of years since the first introduction of the OPEX program. Another limitation related to the quantitative analyses includes that performance effects from OPEX practice implementation typically only show with some time delay. This cannot adequately be accounted, since the collected data only includes a limited number of plants that repeatedly participated and therefore does not allow adequate longitudinal analyses.

Finally, a limitation of this research is related to the recognized context dependency of the studied research phenomenon. The empirical findings reveal on the one hand a great alignment among the subject matter experts on the supportiveness of the identified management behaviors as well as on the potential barriers. On the other hand, they show that the interviewees identify different behavioral implications for the same MC dimensions or management behaviors, depending on context. This applies also to interviewees from the same company. A different sample of pharmaceutical companies or plants could therefore identify additional behavioral MC implications as well as supportive management behavior. The focus on ten companies can therefore be a limitation in terms of the comprehensiveness of the qualitative findings.

Research Outlook

Future research could build upon different findings of this research to quantitatively evaluate the research findings in different contexts.

First, future research could evaluate the comprehensiveness of both the identified management behaviors and the barriers based on a survey that involve a large sample of pharmaceutical companies.

Second, research on pharmaceutical OPEX programs would benefit from quantitatively studying the performance effects of the identified management behaviors, similarly to the analysis of the performance effects of the MC dimensions as part of this research. For this purpose, future research should assess, on the one hand, the level of application of management behaviors as well as the performance of these plants. As part of such a

survey, researchers could also seek to evaluate the proposed content-based categorization as part of this research based on factor analysis. A possible constraint for both analyses is that the identified management behaviors may not be systematically applied to date, so that neither their effects on performance nor their application patterns may be measurable for a large portion of the sample.

Third, future research could quantitatively evaluate the identified performance effects of MC in other industries to evaluate, if the identified moderating effects are similarly observable in other industries. In this context, the study of both moderating effects and their direction could contribute to a better understanding of the impact that the context has on the performance effects of MC.

Finally, future research could enrich the constructed framework for impacting shop floor behavior by assuming effects for selected program theory relations and empirically testing the assumed relations. By doing so, it could contribute to detailing the assumed relations, for example, with main effects, effect directions, or contingency relations.

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Appendix

Appendix A: Research group participants 2018 to 2020 (excerpt of recurring participants)

Company	Location	Position	Interviewed
PharmaCo A	US	Global OPEX Lead	Yes (1)
	CH	Global OPEX Lead Manufacturing	Yes (1)
	CH	OPEX Manager	Yes (1)
	CH	Global Head of OPEX	No
PharmaCo B	CH	Global Head of OPEX Quality Operations	Yes (1)
	CH	Global OPEX Program Manager	Yes (1)
	CH	OPEX Deployment Lead OPEX	No
PharmaCo C	DE	OPEX Deployment Lead Europe	Yes (2)
	BE	Leadership Development Lead Europe	Yes (1)
	US	OPEX Deployment Lead North America	Yes (1)
	IT	OPEX Deployment Director Europe	Yes (2)
	IE	Director Continuous Improvement	No
PharmaCo D	PT	Director OPEX	Yes (1)
	PT	Continuous Improvement Team Lead	No
	PT	Production Director	No
	PT	OPEX Senior Manager	No
PharmaCo E	CH	Managing Director & Site Head	Yes (1)
	FR	Global Transformation Program Lead	No
PharmaCo F	US	Head of OPEX Program Office	Yes (1)
	IE	Global Head of OPEX	Yes (1)
	CH	Global OPEX Lead	No
	CH	Sen. Director Continuous Improvement	No
PharmaCo G	CH	Site Manager	No
	CH	Site Head	Yes (1)
	CH	OPEX Manager	No
	CH	Senior Vice President	No
	CH	Head of Technical Operations	Yes (1)
PharmaCo H	US	Head of OPEX	No
	US	Senior Director OPEX	No
	US	Global Director OPEX	Yes (1)
	US	OPEX Lead	No
	US	Associate Director OPEX	No
PharmaCo I	CH	Head of Global OPEX	No
	UY	Process Specialist	No
	ES	OPEX Manager	No
PharmaCo J	FI	Director Business Planning & Strategy	No
	FI	Production Manager	No
	FI	Director Technical Operations	No

Appendix B: Research group companies

2018	2019	2020
PharmaCo A	PharmaCo A	PharmaCo A
PharmaCo B	PharmaCo B	PharmaCo B
PharmaCo C	PharmaCo C	PharmaCo C
–	–	PharmaCo D
–	–	PharmaCo E
PharmaCo F	PharmaCo F	PharmaCo F
–	–	PharmaCo G
PharmaCo H	PharmaCo H	PharmaCo H
PharmaCo I	PharmaCo I	PharmaCo I
PharmaCo J	–	–

Appendix C: Research group workshop tasks 2019 and 2020

Workshop	Task
<i>What are successful management practices for directing behavior in the context of OPEX programs?</i>	Step 1: Work in groups to identify successful practices for directing organizational behavior in the categories that were preselected for your group. Step 2: Please present your results to the audience. Step 3: Open discussion of results.
<i>What are possible unintended consequences of identified management practices for directing behavior?</i>	Step 1: Work in the groups from the previous day (see above) and identify possible unintended consequences of respective management practices, which were identified by the other groups. Step 2: Rotate to filled out templates of the other groups to review and comment their results. Step 3: Open discussion of results.
<i>What management practices enable sustainable organizational OPEX behavior?</i>	Step 1: Please evaluate the suitability of the practices identified in your group under consideration of the results from the previous session on unintended consequences (see above). Step 2: Please evaluate the identified practices in terms of their impacting on behavior (low to high) and the sustainability of these behaviors. Step 3: Open discussion of results.
<i>What are successful management behaviors that support the six management control dimensions?</i>	Please brainstorm successful management behaviors that support the selected management control dimensions.

Appendix D: Interview Guide Barriers

Case Interview Guideline 1:
Barriers for directing shop floor behavior

Institute of Technology Management
 University of St.Gallen

1. Introduction

- 1 Topic: The role of management control for the implementation of operational excellence (OPEX) in pharmaceutical manufacturing and potential barriers
- 2 Objective: Gain an in-depth understanding of when are which management control practices effective for implementing OPEX in pharmaceutical production
- 3 Interview procedure:
 - i. Introduction to interviewee
 - ii. Understanding the corporate approach to OPEX implementation
 - iii. Understanding the application of management control practices to direct OPEX behavior
 - iv. Understanding the effect of management control practices
 - v. Understanding barriers for directing OPEX behavior
 - vi. Miscellaneous & interview summary
- 4 Next steps:
 - Anonymized documentation of interview
 - Review of write-up by interviewee appreciated
 - Possibility to supplement interview with additional documents, if helpful to further support the case study
 - Cross-case analysis
- 5 Open questions?

Please introduce yourself (role, background regarding OPEX implementation, management support for OPEX, OPEX performance management, etc.)

2. Understanding the corporate approach to OPEX

General information

- When did your company start its OPEX/lean journey?
- What was the focus of early OPEX initiatives to build the foundation for OPEX?
- What is your type of production (Drug substance/API [chemical or biologics]; Drug product [sterile or non-sterile]), site size (in terms of number of FTE), site age, site type (CMO, Generics producer [own brand], Patented drugs producer [own brand])?

Corporate approach

- Who is responsible for OPEX implementation in your organization?
- Do you have a central corporate approach to OPEX implementation that is applied across all production sites?
- If a central corporate approach exists, how do you guide the implementation across different production sites?

1

Case Interview Guideline 1:
Barriers for directing shop floor behavior

- What flexibility do production sites have to develop their own approach to OPEX implementation to fit their specific needs?
- What is your current corporate focus for OPEX capability building?
- Does this focus vary for different production sites?

Strategic OPEX objective

- What is the primary strategic objective you aim to achieve with OPEX?

Key challenges

- What are your key challenges for OPEX implementation?

Lessons learned

- What are your management related key learnings regarding OPEX implementation?

Future activities

- What next steps do you see to further enhance management support for OPEX?

3. Understanding the application of management control practices to direct OPEX behavior

- What are the primary means that your management applies to control and support OPEX behavior?
- What is your approach to promoting or constraining beneficial or disadvantageous quality/OPEX related behavior?
- How do you generally adjust your management approaches to direct OPEX behavior to circumstances (e.g. process type, stage of maturity of technical OPEX)?

Selected OPEX management control mechanisms

1. Visualization
2. Performance measurement
3. Standardized work
4. Employee empowerment
5. Goal setting
6. Training

- What are your main objectives for applying each of these management control mechanisms?
- How do you adjust your management approaches for these mechanisms to circumstance in order to direct OPEX behavior?
- What are other relevant mechanisms that you use to direct OPEX behavior? (e.g. rewards/punishment, etc.). When do you apply these?

Case Interview Guideline 1:
Barriers for directing shop floor behavior

4. Understanding the effect of OPEX management control practices

- What general management practices have been effective to direct OPEX behavior?
- What general management practices have not been effective to direct OPEX behavior?
- What are intended effects of applying the above management control mechanisms?
- What are perceived benefits of applying these management control mechanisms?
- Which of these mechanisms above did you find to be effective for directing OPEX behaviour?
- What challenges for supporting OPEX with each of these management control mechanisms have you recognized? Are any of these challenges due to the regulated environment?
- How do these management control mechanisms affect the effectiveness of technical OPEX practices?

5. Understanding barriers for directing OPEX behavior in Pharma

- What are from your experience general barriers for directing OPEX behaviour in pharmaceutical manufacturing firms? Are any of these challenges due to the regulated pharmaceutical environment?
- What are from your experience specific barriers for directing OPEX behavior with of each of the above management control mechanisms in your organization?

6. Miscellaneous

- Do you address OPEX and quality separately?
- What is your approach to "rewards" and "punishments"?
- What is your approach to other forms of incentives and motivation?
- What are the primary control targets of your performance management systems (input, behavior/how people do the work, output/results of people's work)?
- Is your performance management system focused on performance or on compliance?
- How do you judge the importance of adjusting management approaches for directing OPEX behaviour to circumstance?

7. Interview summary

- Thanks to interviewee for enhancing the research with his/her expertise
- Align on timing for review of interview write-up
- Indicate estimated timing for publication of dissertation
- Clarification of open questions and interview feedback

Appendix E: Interview Guide Management Behaviors

Case Interview Guideline 2: Management behavior	Institute of Technology Management  University of St. Gallen
1. Introduction	
1 Topic: Management behavior and management standard work 2 Objective: Gain an in-depth understanding of <u>how</u> management behaviors can impact the effectiveness of OPEX programs in pharmaceutical manufacturing firms 3 Interview procedure: i. Introduction of interviewee ii. Context of leadership in current OPEX program iii. Role of management behaviors in your OPEX program iv. Desired employee behaviors v. Influence of structural aspects on employee behavior vi. Effective management behaviors vii. Management standard work in your organization ii. Miscellaneous & interview summary 4 Next steps: ▪ Anonymized documentation of interview - Possibility to supplement interview with additional documents, if helpful to further support the case study ▪ Cross-case analysis 5 Open questions?	
<i>Please introduce yourself (job title, role in organization, OPEX background, etc.)</i>	
2. Context of leadership in current OPEX program	
<i>General information</i>	
- When did your company start its OPEX/lean journey? - What is your type of production (Drug substance/API [chemical or biologics]; Drug product [sterile or non-sterile]), site size (in terms of number of FTE), site type (CMO, Generics producer [own brand], Patented drugs producer [own brand])?	
<i>Corporate approach</i>	
- Who is responsible for OPEX implementation in your organization? - Do you have a central corporate approach to OPEX implementation that is applied across all production sites?	
<i>Key challenges</i>	
- What are your key leadership challenges for OPEX implementation?	
1	

Case Interview Guideline 2:
Management behavior

3. Role of management behaviors in your OPEX program

- What role do management behaviors play for your OPEX program?
- What are common undesired management behaviors in your organization?

4. Desired employee behaviors

- What employee behaviors are/are not desired in the context of your OPEX program?

5. Influence of structural aspects on employee behavior

- What formal mechanisms (structures, processes, systems) reinforce OPEX change in your organization?
- Can you produce anecdotal evidence for unintended consequences of the following mechanisms on employee behavior?
 - o Standardization of work
 - o Goal setting
 - o Performance measurement
 - o Visualization
 - o Employee empowerment
 - o Training

6. Effective management behaviors

- Can you think of management behaviors that might have disadvantageous consequences on employee behavior?
- Can you produce anecdotal evidence for effective behaviors for impacting employee behavior for OPEX in your organization?
- What management behaviors do you generally expect to be effective for impacting employee behavior for OPEX in your organization?

7. Management standard work

- How do you define management standard work?
- What are relevant aspects of management standard work in your organization?
- Can you produce anecdotal evidence for:
 - o Successful practices for getting management engagement?
 - o Barriers for implementation of management standard work?

8. Miscellaneous

- What are your management behavior related key learnings from OPEX implementation in your organization?
- What next steps have you planned in your organization to increase effectiveness of management behaviors for OPEX?

Appendix F: Formalization of supportive Management Behaviors as part of MSW (detailed)

	Management Behavior Category	PharmaCo A	PharmaCo C	PharmaCo F
<i>Communication</i>	Cascading Strategy	● MB01, MB03		
	Role Modelling	● MB06, MB08	○ MB05-07	○ MB07, MB09
	Uncovering Guidelines			
	Instilling Improvement Mindset	● MB14, MB16	○ MB12	
<i>Power</i>	Assigning Accountability	● MB18, MB20	○ MB18	○ MB18
	Building Capability	● MB22-23	○ MB22-24	○ MB22-23
	Simplifying	● MB26-27		○ MB26
	Addressing Problems	● MB31-32		
	Resolving ambiguities	● MB34		
<i>Sanction</i>	Confirming Process Execution		○ MB38-40	○ MB38-39
	Recognizing Achievements	● MB41, MB43		
	Confirming Performance Levels		○ MB44-45	
	Conducting Performance Dialogue			

● Explicitly addressed (formalized standard management behaviors)
○ Implicitly addressed (formalized standard management interactions)

Appendix G: Direction of operational performance score items

Dimension	Indicator	Unit	Directional positive	Normalized value	Operational performance
Quality	Rejected batches	%	Down	0 to 1 (1-Percentile)	0 to 1
Quality	Customer complaint rate	%	Down	0 to 1 (1-Percentile)	
Dependability	Unplanned maintenance	%	Down	0 to 1 (1-Percentile)	
Dependability	Production schedule adherence	%	Up	0 to 1 (Percentile)	
Dependability	On-time delivery	%	Up	0 to 1 (Percentile)	
Speed	Deviation closure time	Days	Down	0 to 1 (1-Percentile)	
Cost	Raw material turns	1	Up	0 to 1 (Percentile)	
Cost	Finished good turns	1	Up	0 to 1 (Percentile)	

Appendix H: Measurement items of Management Control constructs

Item	Measurement
VIS1	Performance charts at each of our production processes indicate performance objectives
VIS2	Charts showing current performance status are posted on the shop floor and visible for everyone
VIS3	Charts showing current tact times and schedule compliance are posted on the shop floor and visible for everyone
VIS4	Technical documents and workplace information are posted on the shop floor and are easily accessible and visible for everyone
STD1	We emphasize standardization as a strategy for continuously improving our processes, machines and products
STD2	We use our documented operating procedures to standardize our processes
STD3	Optimized operating procedures are documented as best-practice processes and rolled-out throughout the plant
PM1	We continuously measure the quality of our processes by using process measures
PM2	Our process measures are directly linked to our plant objectives
EE1	Shop floor employees actively drive suggestion programs
EE2	Our plant forms cross-functional project teams to solve problems
EE3	We have implemented tools and methods to deploy a continuous improvement process
GS1	Our vision, mission and strategy are broadly communicated and lived by our employees
GS2	Goals and objectives of the manufacturing unit are closely linked and consistent with corporate objectives. The production site has a clear focus
GS3	The overall objectives of the production sites are closely linked to the team or personal objectives of our shop floor teams and employees
TR1	Each of our employees within our work teams is cross trained so that they can fill-in for others when necessary
TR2	At our plant we have implemented a formal program to increase the flexibility of our production workers. Employees rotate to maintain their qualification
TR3	We continuously invest in training and qualification of our workers. We have a dedicated development and qualification program for our production workers

Appendix I: Operational performance measurement

Indicator	Definition
Rejected batches	Number of rejected batches as a percentage of all batches produced
Customer complaint rate	Number of complaints as a percentage of all customer orders delivered
Unplanned maintenance	Proportion of unplanned maintenance work as a percentage of the overall time spent for maintenance
Production schedule adherence	Number of orders finished in the correct week and volume (+/- 10%) of total number of orders planned for completion that week
On-time delivery	Perfect order fulfilment to your customer as percentage of orders shipped in time from your site (+/- 1 days of the agreed shipment day), in the right quantity (+/- 3% of the agreed quantity), and in right quality
Deviation closure time	Number of deviations per month that arise from raw materials purchased, production components (equipment), and product or process specifications
Raw material turns	Annual cost of raw materials purchased divided by the average raw material inventory
Finished good turns	Annual cost of goods sold divided by the average finished goods inventory

Curriculum Vitae

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Work Experience

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05/2015 – 10/2015	MAN Diesel & Turbo SE , Augsburg, Germany Master Thesis Value Engineering
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