University of St.Gallen

Institute of Technology Management

AI in QC Labs

St.Gallen QCEx Meeting 1
Orientation Round (add-on) – AI
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Jessica Helbling, Prof. Dr. Thomas Friedli - University of St.Gallen

Current AI Strategy

What is your current strategy for adopting AI in QC? What criteria do you use to evaluate and select AI technologies? How do you ensure that the selected AI tools align with your needs?

The current AI strategies across companies in the QCEx community are largely in an exploratory phase, with a stronger focus on QA and R&D than on QC. Most companies have chosen not to position themselves as early adopters, often citing high costs and unclear regulatory expectations. Instead, they are prioritizing foundational work – such as educating employees, identifying internal use cases, and establishing AI governance frameworks. Several companies have created dedicated AI groups or ambassadors to drive internal awareness and manage change, supporting a broader cultural transformation.

Where AI is being implemented, it often serves as a general assistant tool in non-critical areas. Some companies are gathering data and building cross-functional strategies to guide future deployment. However, a clear QC-specific AI strategy is not yet in place in most cases. Data readiness, particularly the lack of structured and standardized formats, remains a key obstacle.

Overall, companies are laying the groundwork – focusing on capability building, internal alignment, and digital infrastructure – in preparation for more targeted AI integration in QC functions.

Specific Use Cases of AI

What specific use cases of AI have you implemented in QC? Can you provide examples of AI applications in both GxP and non-GxP activities?

Current AI use cases are primarily focused on non-GMP environments, where regulatory risks are lower and implementation is more flexible. Companies are leveraging AI to automate routine administrative tasks, consolidate information, generate documents, and support investigations. These applications help reduce manual workload, especially for repetitive tasks such as SOP writing, meeting documentation, and deviation handling.

Some companies are piloting more advanced applications, including optical evaluation in microbiology, chromatography data review, and report generation based on raw data. Additionally, AI is being used to gather and compare data across systems, create flowcharts, and assist in root cause analyses. These pilots indicate a growing interest in applying AI to areas that benefit from efficiency and standardization. However, use cases specific to QC remain limited. Most QC teams are currently participating in broader quality-focused initiatives rather than driving their own AI agendas. The observed trend suggests that AI is gradually being integrated where it supports knowledge consolidation, improves decision-making, and reduces time spend on low-value activities.

Impact & Benefits of AI

What benefits have you observed from using AI in QC (e.g., regarding measurement consistency, error reduction, testing times, standardization of testing procedures)?

The anticipated benefits of AI span both operational efficiency and quality improvements. Companies report early signs of time savings, reduced manual errors, and shorter cycle times, particularly in administrative and investigative processes. AI is also seen as a tool for standardizing outputs, increasing process consistency, and supporting RFT.

Beyond measurable gains, several soft benefits are emerging. These include increased employee motivation due to reduced repetitive work, a stronger focus on critical thinking, and improved access to insights.

In the long term, AI is expected to support better CAPA outcomes, enhance training effectiveness, and improve trending and deviation management. While the full impact remains difficult to quantify at this stage, early pilots suggest that AI offers value both in enhancing quality and optimizing resources. The challenge now lies in scaling these benefits into regulated environments without compromising compliance or data integrity.

Challenges & Regulatory Considerations

What specific challenges have you faced when implementing AI in QC (e.g., regarding regulatory requirements & inspections)? What lessons have you learned and what strategies have proven effective in overcoming these challenges?

Despite promising developments, the implementation of AI in QC faces significant challenges, particularly in the GMP environment. A major concern is the lack of clear regulatory guidance from health authorities. Without defined expectations for validation, companies hesitate to integrate AI into GMP-critical processes. Data quality and structure also present persistent issues, with many systems not yet capable of supporting automated or AI-driven workflows.

Skills and resource availability are another barrier. The shortage of data scientist, limited IT support, and legacy system constraints hinder broader adoption. Organizational mindset is also a factor – teams must adapt to new technologies while maintaining accountability and compliance. Several companies highlight the complexity of retraining AI models, ensuring reproducibility, and managing frequent software updates. Ownership of data, especially when using external vendors, adds an additional compliance concern.

In summary, the technical potential of AI is evident, but progress in QC will require overcoming regulatory uncertainty, improving data infrastructure, and developing internal capabilities.

Cross-Company Reflection

Across the board, companies share a sense of cautious optimism. While approaches differ slightly, most companies are at a similar stage: testing use cases through pilot projects, aligning internal strategies, and preparing for broader adoption. The focus in many cases is still on manufacturing, QA, R&D, with QC recognized as foundational but not yet prioritized in AI deployment. There is widespread agreement that structured data, and standardized processes are prerequisites for meaningful AI integration.

The environment remains complex, and readiness is uneven. Nonetheless, companies are not waiting for perfect conditions – they are experimenting, learning, and gradually building maturity. Expectations are high, but there is also growing recognition that AI is not a solution in itself. Its value depends on how well it supports actual business needs. Looking ahead, companies will need to solidify their AI strategies, particularly for QC, and continue fostering a mindset that sees AI not just as a tool for automation, but as a lever for quality and innovations.