



University of St.Gallen

Institute of Technology Management

Artificial Intelligence in Pharmaceutical QC Labs

St.Gallen QCEx Meeting 1
Orientation Round – Meeting Reflection Paper
May, 2024

QC*Ex*
2024

Lorenzo Pirrone, Jessica Helbling, Prof. Dr. Thomas Friedli - University of St.Gallen

Role of Artificial Intelligence

How do you expect AI transforming QC practices in the future, and which specific areas do you think AI will impact the most?

The QCEx community foresees various impacts of digital technologies, in particular Artificial Intelligence (AI) on QC laboratory practices. Key areas where AI is expected to have the most significant impact include lab technician support, scheduling and capacity planning, or deviation and quality system improvement.

In the area of lab technician support the community expects that AI speeds up an individual's work by optimizing the process that focuses on the non-testing work. In that regard protocols and standard operating procedures etc. are likely to be generated by technology. Furthermore, AI in the near future will be able to conduct pharmacopoeia compliance checks, semantic searches, method harmonization, template creation, or write-ups. As a personal assistant, various copilot and ChatGPT applications will continue to find their way into the daily work of lab technicians. Besides that, AI, according to the community, can streamline training processes by reducing the time required, tailoring training to individual experience levels, and enhancing the effectiveness of onboarding and continuous education.

In the area of scheduling and capacity planning, AI is expected to optimize demand and capacity ultimately supporting effective allocation of resources which will streamline operations and reduce downtimes. Scheduling is anticipated to happen more predictive than reactive utilizing big data to propose optimal solutions for daily job planning and streamlining human and technological capabilities as well as availabilities to test for the market and the customer.

In the area of deviation and quality system improvement, AI can identify variability in data related to analysts, instruments, and reagents, helping to review root causes, recurring deviations, and trends. Additionally, AI supports the creation and understanding of deviation management documents, writes laboratory investigation reports (LIRs), and spots patterns in large datasets that are beyond human processing capabilities.

Overall, the community presents various confident considerations that, ultimately help realize the lab of the future. In that vein concepts like review by exception, AI supported chromatograms, optimized testing schedules, automated image recognition for plate reading, and continuous monitoring are soon to be realized. However, with all the enthusiasm in the industry, some companies also raise concerns: If everything is connected and if more and more AI models will be introduced, what happens if different models come to different solutions?

Use Cases of Artificial Intelligence

What specific examples can you share where AI-driven optimizations resulted in notable time savings or efficiency improvement within QC processes?

Although differences can be found between companies, the community shows: AI is gradually being integrated into QC practices. Current applications span from AI camera systems, data analytics, AI supported Raman applications, or AI created deviation reports. Moreover, pilot projects and limited

roll-outs are underway, focusing on e.g., transforming process flow maps into SOPs, automating data evaluation, and using AI for chromatogram integration and real-time data monitoring to improve efficiency and compliance. Companies that have so far not integrated sophisticated AI applications already benefit from efficiency gains in QC due to necessary data integration in preparation of those.

Cost vs Benefit

What methods or criteria do you use to evaluate the cost-benefit-ratio when considering your adoption of new technologies in QC?

The community shows that cost-benefit considerations are conducted through business case evaluations which, in addition to cost factors also acknowledge softer elements and strategic, quality and compliance aspects. Companies find it difficult to “put a money tag” on AI use cases, but overcome such pitfalls by joined discussions together with controlling and cross-functional teams. Once a business case is approved, use case realization happens through a pilot, proof of concept, and roll-out across several labs,

How do you measure the success of new technologies once they are implemented? What specific metrics/criteria do you use to evaluate the success/effectiveness?

The above mentioned relationship with controlling is vital for evaluating savings, which include reductions in instrument downtimes, lead times, deviations, and Out of Specification (OOS) results, alongside basic assessments of time, cost, and people investment for business case evaluations. Metrics such as compliance increase, infrastructure savings, user satisfaction, and cycle times are monitored, with KPIs defined before project initiation and success measured through analysis of key metrics and cost versus time savings, all contributing to staying competitive and demonstrating the benefits of digitalization through pilot phases and roll-outs focused on efficiency, compliance, and overall savings. Particularly, significant reduction for LIR writing and LIR closure times have been presented at the QCEx meeting.

Monitoring Trends and Innovation

How do you stay informed about emerging trends and practices in QC regarding new technologies (e.g., strategy for market screening, dedicated teams, best practices, ...)?

The community conducts various sensing activities to stay ahead of competition and being informed about upcoming technologies and trends in AI. Depending on the company, these tasks are performed by different organizational units. For example, in some cases, dedicated functions outside of QC support with a trend radar. These can be part of the global R&D, IT, digital technology, digital product or Operational Excellence team. Other companies build dedicated global QC councils, lab center of excellence or lab of the future teams to learn and share knowledge. In general, sensing activities can either be internally or externally oriented. Internal orientation is mostly expressed in best practice sharing between QC teams and industry publications as well as press research. External orientation is represented by attending conferences, forums, roundtables, and symposia such as the QCEx, Paperless Lab Academy or Analytica Fair. Moreover, companies engage in

benchmarking exercises or software vendor meetings (e.g., Empower, Agilent, LIMS users conference). All companies state that networking, both internally and externally is crucial for monitoring trends and innovation.