

GENAI IN LIFE SCIENCES BLOG

Generative AI's elevating standards: The future of quality management



In the dynamic landscape of life sciences, the excitement and curiosity around generative artificial intelligence (GenAI) cannot be understated. From speaking to colleagues across the industry, many would like to know how the technology will affect future business and how they can take steps to best leverage Generative AI's potential.

One of the most impactful shifts is likely going to be in quality management in manufacturing. As technology and regulatory forces shift, an evolving picture of the future of quality management comes into view.

A glimpse into the future

The future of quality management shifts the focus from time-consuming, retrospective investigations to one dominated by proactive interventions in near real time. In this new paradigm, assistive GenAI tools simplify workflows and tasks for quality control associates across the quality event management life cycle.

From auto-generating descriptions of quality events to triaging them to appropriate workflows, AI can accelerate the reaction time. Even more, GenAI technologies have the unique ability to investigate quality events by tapping into institutional knowledge, which often is unavailable in subjective, manual investigations. Where laborious effort was put into documentation and reporting, this will now be ready to go within minutes.

Generative AI is accelerating these trends by knocking down barriers to data analysis; accelerating documentation and review cycles; and expanding the number and efficacy of the quality management methods available.

Potential outcomes enabled by Generative AI

Quality strategy	The creation of new quality capabilities and rapid scaling of these across global sites (e.g., generation and review of SOP documentation)
Quality analytics	The democratization of data with more data and lower barriers to analyze resulting in greater insight (e.g., parsing through patient experience data for insights)
Quality process excellence	The automation of process and SOP creation, and SOPs and optimization, with new learning and dissemination approaches (e.g., generated equipment walk-throughs)
Quality management systems	The rise of self-learning quality management systems that can intelligently manage events (e.g., event triage and generated recommendations for responding actions)
Quality risk management	The increased traceability and scrutiny of risk factors (e.g., integrated review of supplier shipment certificates)
Rapid regulatory response	The acceleration of the intake, triage, investigation, and communication of quality events (e.g., generation of draft report write-ups from quality events)

How can I successfully implement Generative AI?

Successfully implementing Generative AI requires developing a thoughtful strategy—one that combines existing and new technologies under a governance structure that enables core quality capabilities and is built around collaboration with industry associations and regulators.

As you craft your approach, consider the following:

- 1. Focus on the problem, not the solution.** Generative AI is another tool in the box. Focus on signature business problems and select the appropriate solution. Often, this requires a combination of techniques.
- 2. Platforms, not point solutions.** Individual solutions may provide value, but their proliferation will start to cannibalize that value rapidly—consider focusing on multi-use platforms that drive value across multiple domains.
- 3. It's not all about efficiency.** Doing the same activities faster and cheaper will unlock short-term value. Focus on new capabilities and you will likely be able to create a continuous source of value that can make quality management a competitive differentiator.

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Want to learn more?

As you examine what the future of quality management looks like for your organization, reach out to us to learn how we can help you adopt a strategic Generative AI approach.

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