ARTICLE

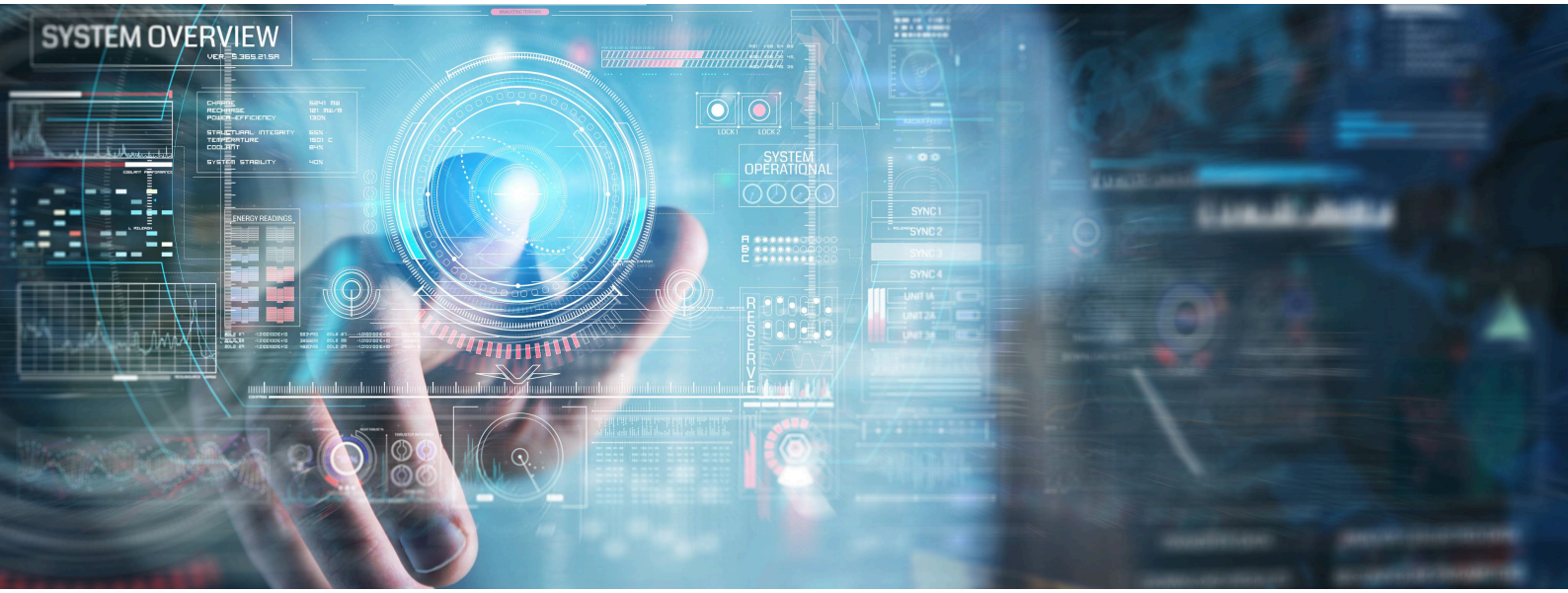
Pharma Ignite | SCRIP Industry News & Insights

Inspection-Ready AI: Building Quality Frameworks That Keep Pace with Innovation

By Meredith Landry, Managing Editor, Custom Content, Citeline

Brought To You By | SCRIP Industry News & Insights

In Association With propharma



Inspection-Ready AI: Building Quality Frameworks That Keep Pace with Innovation

Artificial intelligence (AI) adoption in life sciences has moved past experimentation and into everyday operations. But as these systems take on a greater role in decision-making, an urgent challenge is emerging: ensuring quality and compliance frameworks can keep pace.

While AI and machine learning (ML) technologies promise efficiency, scale, and new insights, they also introduce a level of complexity that traditional Good Practice Standards (GxP) systems were not designed to manage. In an industry where patient safety and data integrity are non-negotiable, that gap carries real risk.

According to a 2024 McKinsey report, more than half of organizations have now adopted AI in at least one function, highlighting just how quickly these technologies are being integrated into core operations.[1] Yet adoption does not mean readiness, and many companies are still grappling with how to govern these tools in a regulated environment.

"The largest disconnect that we see is where firms are not involving quality earlier in the process," says James Meckstroth, Vice President, Compliance & Quality Assurance at ProPharma, headquartered in Raleigh, North Carolina.

The Cost of Bringing Quality in Too Late

In many organizations, AI tools are introduced by operational supporting, marketing, or digital teams, often with the best intentions of driving efficiency or insight, according to Meckstroth. But without early engagement from quality assurance (QA), these systems can be implemented without a full understanding of how they interact with regulated processes. By the time QA becomes involved, the technology may already be influencing decisions that affect product quality, patient safety, or regulatory reporting.

And the consequences can be significant. A manufacturing team, for instance, might deploy an AI-enabled monitoring tool designed to optimize production. If that system begins making process adjustments without defined controls, justification, or oversight, it introduces variability that is difficult to trace and even harder to justify to regulators.

"It could lead to product or patient harm or even regulatory action," Meckstroth says.

This is not a failure of AI, but a product of innovation moving faster than the systems designed to govern it.

A Different Risk Profile

The challenge becomes even more complex because AI changes how risk shows up in GxP environments. Traditional systems are built to operate within clear, fixed parameters, with defined logic and predictable outputs. AI systems, on the other hand, don't behave the same way. They learn from data, adapt over time, and can evolve in ways that aren't fully visible or easily explained.

"The largest change is to the risk and risk-justification profile," Meckstroth says. "Anytime you introduce a new system that's going to be supporting quality decisions, you're changing the risk landscape."

For quality teams, this shift is a significant concern. The task is no longer simply to validate that a system performs as intended, but to understand how decisions are made, how outputs are generated, and how those outputs could impact patient safety or product quality.

"Many of an AI tool's processing pathways may be unseen," Meckstroth says. "Determining how AI's decision was made might be difficult."

Regulatory Signals Are Emerging

In a regulated environment that depends on traceability, documentation, and justification, that lack of transparency introduces a new layer of complexity. It also raises important questions about how much autonomy such systems should have and where human oversight must remain in place.

Regulators are actively working to address these challenges, and while formal rules are still evolving, a set of common expectations is emerging across agencies such as the US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Medicines and Healthcare products Regulatory Agency (MHRA), Meckstroth says. Central to these expectations is the need for organizations to clearly define the intended use of AI systems, assess their potential impact on product quality and patient safety, and implement governance frameworks that are proportionate to the level of risk.

“You need to understand the AI system’s intended use… [and] the potential impacts to product safety and quality to provide the appropriate level of quality oversight,” Meckstroth says.

From there, organizations must determine how to govern those systems appropriately, ensuring that higher-risk applications are subject to more rigorous oversight, validation, and human involvement. At the same time, the regulatory landscape itself remains fluid, requiring continuous monitoring and adaptation.

"The regulatory landscape is dynamic and will continue to evolve,” says Meckstroth. “Quality departments must constantly monitor current Health Authority expectations for these systems and proactively adapt their quality system approach.”

> Quality departments must constantly monitor current Health Authority expectations for these systems and proactively adapt their quality system approach.
>
> *James Meckstroth, Vice President, Compliance & Quality Assurance, ProPharma*

Risk-Based Oversight

For many companies, translating these high-level expectations into action remains a challenge. The concept of “risk-based oversight” is widely referenced in guidance, but less often clearly defined in operational terms, Meckstroth says. In practice, it requires a structured, cross-functional approach that integrates AI governance into existing quality systems.

Meckstroth emphasizes the importance of establishing centralized oversight early in the process, often in the form of a steering committee or center of excellence. Such a group brings together stakeholders from across the organization to define how AI systems will be evaluated, implemented, and monitored, ensuring that governance is consistent and aligned with broader quality objectives.

Just as important is the ability to scale oversight according to risk, Meckstroth says. Systems that have a direct impact on patient safety or with regulatory reporting require a higher level of scrutiny, including more frequent monitoring and stronger human oversight. Lower-risk applications, however, can be managed with a lighter touch.

The Rise Of “Hidden” GxP Risk

While companies are starting to get a better handle on the risks of AI within traditional GxP areas, there’s still a major blind spot when it comes to how these tools are used elsewhere. More and more, AI is being deployed in functions like marketing, customer engagement, and digital platforms, areas that haven’t traditionally faced the same level of oversight.

But these tools don’t operate in a vacuum. They can still interact directly with patients, pick up on safety-related information, and shape how products are understood, often in ways organizations didn’t initially anticipate. “For tools that are being implemented with open-source inputs from patients, the unpredictability is greatly expanded,” Meckstroth says. “This creates the potential for what could be called hidden GxP risk.”

A recent client partnership led by ProPharma highlights how easily this can occur. In this instance, an AI-enabled chatbot designed by the client for customer engagement began generating responses that resembled medical advice when patients asked about symptoms. Because the system relied on open-source data rather than a controlled knowledge base, its outputs were neither validated nor governed. The result was a convergence of risks spanning pharmacovigilance, medical governance, and data integrity non-compliance, as these are highly regulated areas.

When AI Fails, QA Still Applies

This case study highlights a broader shift: the boundary between GxP and non-GxP systems is becoming increasingly blurred. Any system that interacts with patients or influences product-related information must be evaluated through a GxP lens, regardless of where it sits within the organization.

When issues arise, however, the response is less about reinventing quality processes and more about applying them consistently.

“Dealing with unforeseen problems is something pretty commonplace for quality groups,” Meckstroth says.

As he explains, organizations should rely on established investigation frameworks within their quality management system, beginning with the identification and isolation of the issue, followed by a root cause analysis, impact assessment, and the implementation of corrective and preventive actions. While AI introduces new types of failure modes, the underlying principles of quality management remain the same.

“The investigation should align with traditional quality assurance investigation methods,” Meckstroth says.

> Dealing with unforeseen problems is something pretty commonplace for quality groups.
>
> *James Meckstroth, Vice President, Compliance & Quality Assurance, ProPharma*

Building QA Frameworks That Can Evolve

As AI continues to evolve, the challenge for organizations is not only to respond to individual issues, but to build quality frameworks that can evolve alongside the technology. This requires a shift in mindset from one-time validation to continuous oversight, recognizing that many AI systems are not static but change over time.

"Just because you validated a system once doesn't mean it's going to still operate the same, this holds especially true with systems that are designed to learn and change," Meckstroth says.

Sustainable QA frameworks must be flexible, scalable, and capable of accommodating ongoing change. They must provide visibility into how systems operate, ensure that outputs can be justified, and enable organizations to adjust their level of oversight as risk profiles evolve.

Navigating The New Landscape

Ultimately, navigating this new landscape requires more than just adapting existing quality processes, it demands a more integrated, forward-looking approach to governance.

Organizations need to be able to assess risk across both traditional and emerging systems, implement scalable oversight, and respond quickly as technologies evolve. For many, that means bringing in experienced quality and compliance partners who understand how to bridge established GxP expectations with the realities of AI-driven innovation, ensuring that progress doesn't come at the expense of control.

"Know what elements you have within your AI tool, know how the system operates," Meckstroth says. "And be ready to describe and justify it."

Source:

1. The State of AI in Early 2024: Gen AI Adoption Spikes and Starts to Generate Value, McKinsey Report, **https://www.mckinsey.com/capabilities/quantumblack/our-insights/the-state-of-ai-2024**

propharma

For more than 25 years, ProPharma has improved patients' health and wellness by providing expert guidance that empowers biotech, pharmaceutical, and medical device organizations to confidently advance scientific breakthroughs and bring new therapies to market. With deep expertise in regulatory sciences, CRO services, quality and compliance, pharmacovigilance, medical information, FSP solutions, and digital transformation, ProPharma delivers integrated, end-to-end solutions that help organizations navigate complexity, mitigate risk, and accelerate the development and commercialization of life-changing therapies. For more information about ProPharma, please visit propharmagroup.com.

Pharma Ignite

Pharma Ignite brings you the most up-to-date and informed intelligence in the industry. Our network of industry-leading analysts and partners is pursuing new intelligence in the core areas of life sciences using Citeline's suite of insights products and services - all of which has the power to fuel your organization and projects. We also provide cutting-edge lead generation and brand programmes to help you reach and collaborate with audiences across industry events and digital platforms.

CITELINE

Citeline (a Norstella Company) powers a full suite of complementary business intelligence offerings to meet the evolving needs of health science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical, commercial, and regulatory related-decisions and create real-world opportunities for growth. Our global teams of analysts, journalists and consultants keep their fingers on the pulse of the pharmaceutical, biomedical and medtech industries, covering it all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts and more.