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AI and Automation

Governance for Rising Technologies

by Sivakumar Kalidoss, Sun Chau Siu, Kaisong Zhou, and James Colley

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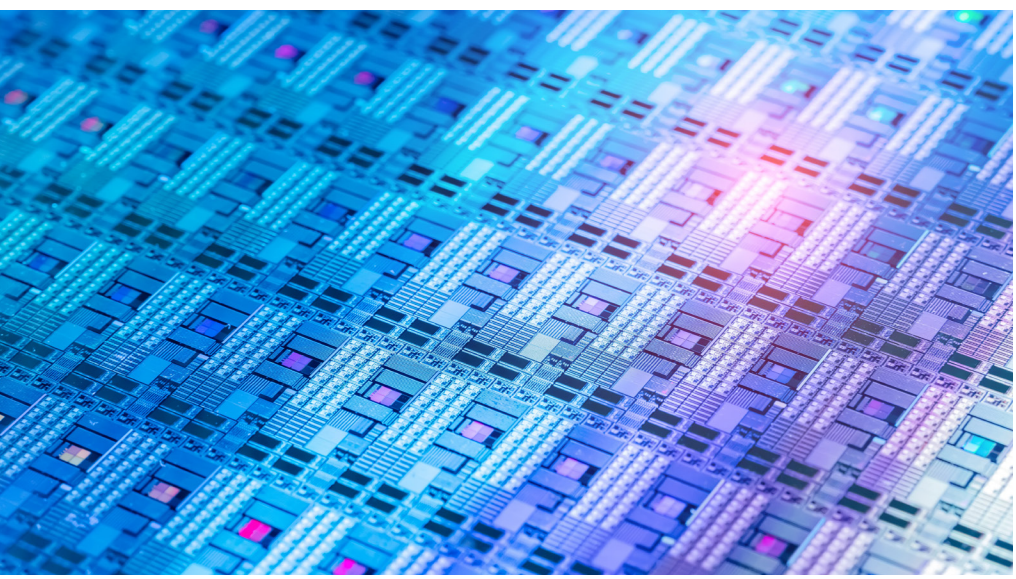
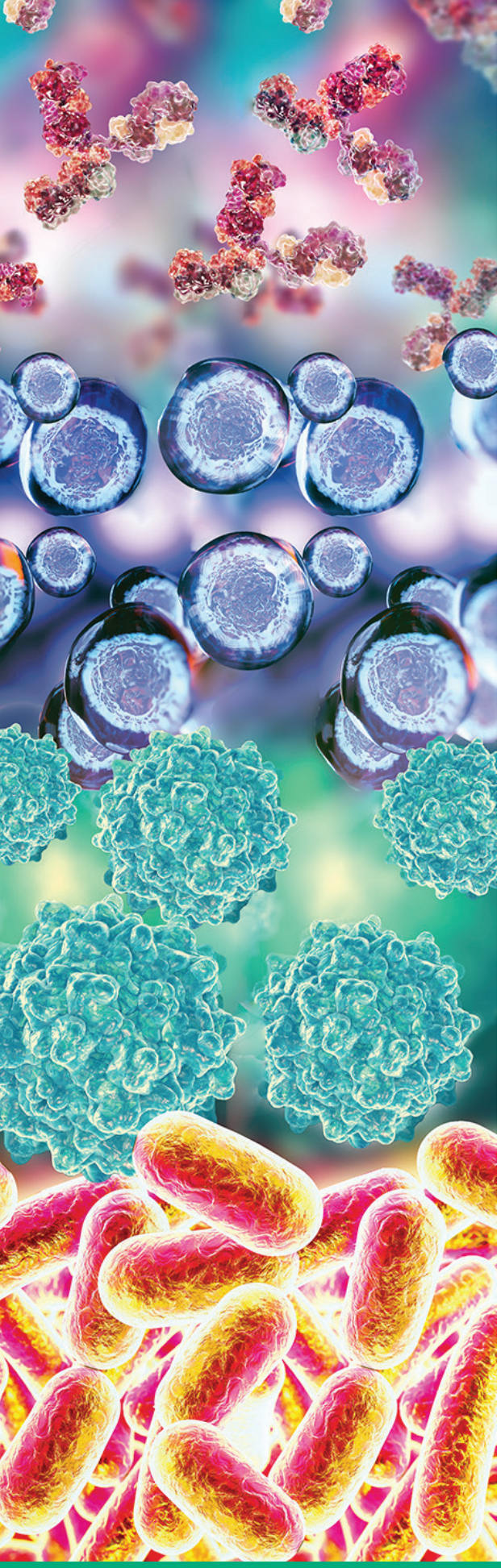


Adoption of artificial-intelligence (AI) and machine-learning (ML) tools offers great promise to the future of biomanufacturing. But regulatory guidances must still evolve for such novel technologies to reach their full potential without impacting product quality and safety. In this eBook, experts discuss practical standards and regulatory governance for AI tools and software in biomanufacturing. Pictured (left) is macro photography of a silicon wafer with microchip patterns for AI hardware.



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Partners for *Life*

Beyond Installation, Operational, and Performance Qualifications

A Risk-Based Validation Framework for AI-Driven Software in GxP Environments

Sivakumar Kalidoss

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Computer system validation (CSV) has governed good-practice (GxP) software compliance for over three decades, and for deterministic systems, it works well. But software driven by artificial intelligence (AI) presents a fundamentally different challenge. Machine-learning (ML) models, neural networks, and adaptive decision engines do not behave identically across all inputs, and many are designed to evolve over time. Applying conventional installation, operational, and performance qualification (IQ, OQ, PQ) protocols to such systems only captures performance at a single moment and does not provide durable assurance of ongoing fitness for purpose. The industry must now close that validation gap.

A regulatory foundation already exists. The US Food and Drug Administration's (FDA's) 2021 AI/ML Action Plan introduced the concept of a *predetermined change control plan* (PCCP), a preapproved framework defining what changes a model may undergo without triggering full resubmission (**1**). The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q9 guidance provides a risk-based lens to calibrate validation rigor (**2**). ICH Q10 establishes the principles for knowledge management and continual improvement that support life-cycle–based validation (**3**). And the second edition of the good automated-manufacturing practice 5 (GAMP 5) framework explicitly accommodates agile and iterative development (**4**). The scaffolding is in place; what is needed is practical architecture.

Building a Practical Framework

A practical framework for AI validation in GxP environments rests on three principles.

Risk Stratification by Patient and Product Impact: Not all AI applications carry equal risk. An advisory tool that drafts

deviation narratives for human review differs fundamentally from a model whose output directly triggers a batch-disposition decision. Classify AI applications by directness of impact and degree of human oversight, then apply proportional validation rigor. High-impact, low-oversight systems demand stringent controls; low-risk advisory tools warrant a lighter, but still documented, approach.

Life-Cycle Integration Over Point-in-Time Qualification: Establish baseline performance metrics at initial validation — e.g., precision, recall, false-positive rate — and implement continuous monitoring to detect model drift before it affects product quality or patient safety. Statistical process control methods and continued process verification (CPV) principles from the FDA's 2011 process validation guidance can translate directly (**5**). For AI systems, validation is a program, not an event.

Predetermined Change-Control Boundaries: During initial validation, define what changes are permissible without triggering revalidation and which thresholds require partial or full review. A documented PCCP for each AI application, approved through the quality system, provides both operational flexibility and an inspection-defensible regulatory posture. It prevents both overburdening the compliance function and under-governing the system.

Any AI governance framework must also address data integrity. Algorithmic decision logs, which capture model version, input data, output, and confidence scores, are GxP records and thus must meet ALCOA+ requirements — meaning that such logs are *attributable, legible, contemporaneous, original,* and *accurate* (**6, 7**). Such architecture should be built in during validation planning, not retrofitted after deployment.

Validation professionals are uniquely equipped to lead that work. Risk-based thinking, regulatory fluency, and documentation discipline are precisely the competencies that AI governance requires. Organizations that begin building structured AI validation frameworks now, grounded in existing regulatory principles and proportionate to risk, will be well positioned for inspections, able to scale AI adoption responsibly, and poised to leap ahead of those waiting for guidance that may take years to fully materialize.

Classify AI applications by directness of **IMPACT** and degree of human **OVERSIGHT,** then apply proportional validation rigor.

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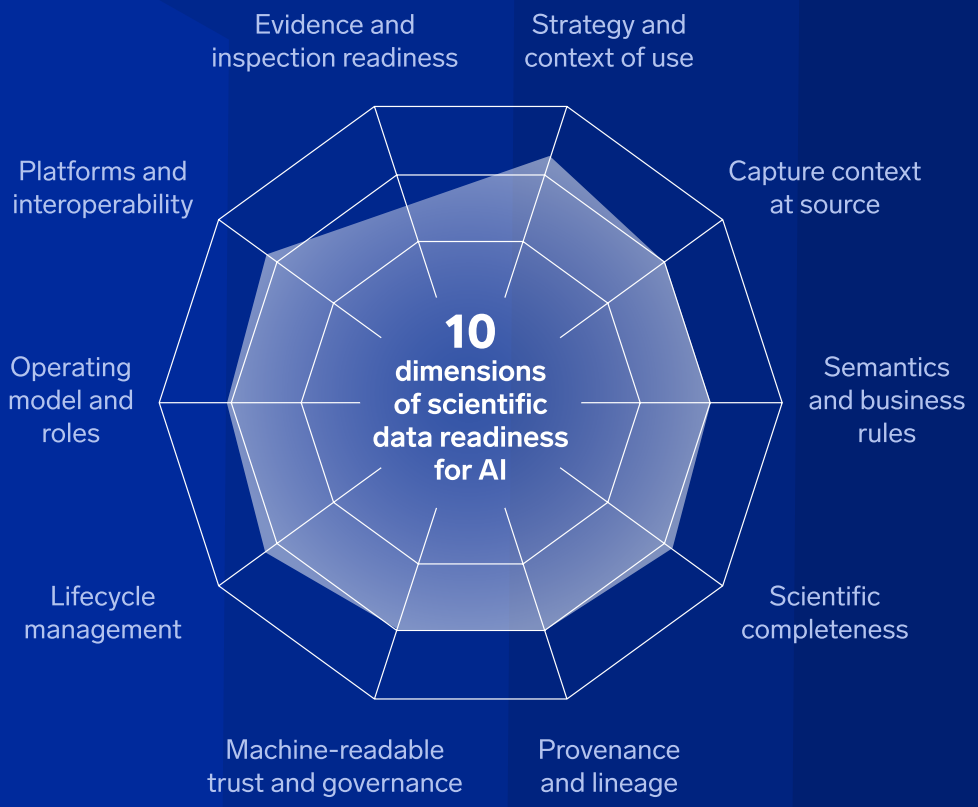

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Artificial Intelligence in Good Manufacturing Practices

Governing the Emerging Challenge of Algorithmic Control

Sun Chau Siu and Kaisong Zhou

Artificial intelligence (AI) is rapidly transitioning from exploratory analytics to operational deployment within biomanufacturing. Across the industry, data-driven technologies are being applied to enhance process understanding, improve operational efficiency, and strengthen manufacturing robustness. As those capabilities move closer to influencing decision-making within good manufacturing practice (GMP) environments, the central question is no longer whether AI can be used in manufacturing, but instead how it can be governed within established regulatory frameworks.

Although adoption remains uneven, many biomanufacturers and contract development and manufacturing organizations (CDMOs) are evaluating how machine-learning (ML) tools can support manufacturing analytics, predictive maintenance, and enhanced process monitoring across complex production environments. Industry reports indicate that biopharmaceutical companies are assessing AI and advanced analytics as part of broad manufacturing initiatives and supply-chain digitalization strategies (**1, 2**).

At the same time, regulatory expectations surrounding AI are still evolving. Although health agencies and international organizations have begun publishing discussion papers and guidance on AI, the practical implications for biopharmaceutical manufacturing remain a subject of ongoing interpretation. As AI systems begin to influence decisions in GMP environments, organizations must maintain control over algorithmic systems that can evolve over time.

A fundamental gap exists between traditional GMP control paradigms and the dynamic behavior of algorithmic systems. Traditional GMP frameworks were developed around deterministic systems and fixed process models. AI introduces new dynamics that require organizations to reconsider governance, validation, and life-cycle oversight.

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Robotic arm and processing tank within the fill–finish cleanroom at Altruist Biologics, enabling automated material transfer to an isolator (HTTPS://WWW.ALTRUISTBIO.COM)

Emerging Regulatory Perspectives on Artificial Intelligence

Regulatory perspectives on AI are beginning to show broad conceptual alignment across major global authorities, reflecting a shared recognition that traditional validation paradigms are insufficient for governing dynamic, data-driven systems. The US Food and Drug Administration (FDA) has articulated a risk-based framework for evaluating AI models in a draft guidance, emphasizing context of use, model risk assessment, and credibility evaluation (**3**). In parallel, the European Medicines Agency (EMA) has provided a complementary perspective through its reflection paper on the use of AI across the life cycle of medicinal products, highlighting the importance of model interpretability, data quality, and ongoing performance monitoring as operating environments evolve (**4**).

More recently, a joint initiative between the EMA and the FDA has further advanced this alignment by publishing the *Guiding Principles of Good AI Practice in Drug Development* (**5**). This document establishes a shared set of guiding principles centered on risk-based oversight, a clearly defined context of use, robust data governance, and life-cycle management, including continuous monitoring and periodic reevaluation of AI systems.

Complementing those developments, the European Union's (EU's) Artificial Intelligence Act introduces a broad, cross-sector regulatory framework based on risk classification (**6**), whereas the draft Annex 22 of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) emphasizes the need to integrate AI systems into existing pharmaceutical quality system (PQS) structures (**7**). At the operational level, the FDA's computer software assurance (CSA) framework (**8**) reinforces a shift from static validation toward life-cycle–based assurance, focusing on maintaining fitness for intended use through ongoing monitoring and risk-based verification. Those frameworks differ in scope, maturity, and regulatory intent; however, they collectively signal a directional shift toward life-cycle–based oversight of data-driven systems.

In practice, those expectations translate into a clearly defined context of use, risk-based validation commensurate with good-practice (GxP) impact, robust data governance, and life-cycle management embedded within established PQS processes. Annex 22 also emphasizes the importance of model transparency, traceability of data and model versions, and the ability to demonstrate ongoing control through monitoring and periodic review (**7**). Successful adoption of AI in GMP environments will depend not only on model performance, but also on the ability to sustain control through effective integration within a PQS.

Governance of AI systems is evolving from an approach centered on **ONE-TIME** validation toward a life-cycle–based paradigm requiring **CONTINUOUS** assurance of performance, reliability, and contextual validity.

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Taken together, such developments indicate a clear regulatory trajectory: Governance of AI systems is evolving from an approach centered on one-time validation toward a life-cycle–based paradigm requiring continuous assurance of performance, reliability, and contextual validity. In that emerging framework, maintaining control over AI systems is not a discrete activity, but an ongoing process embedded within the PQS. Figure 1 illustrates that life-cycle–based concept.

Operational Applications of AI in Biomanufacturing

Early implementations of AI tools are emerging across both upstream and downstream processing and manufacturing support systems. As those applications begin to influence operational decision-making in regulated environments, the focus shifts toward how such systems can be governed within established GMP frameworks.

In cell-culture operations, ML models are being investigated to predict nutrient depletion, metabolite accumulation, and culture trajectory, enabling more proactive process control strategies (**9, 10**). Downstream groups are exploring predictive models for

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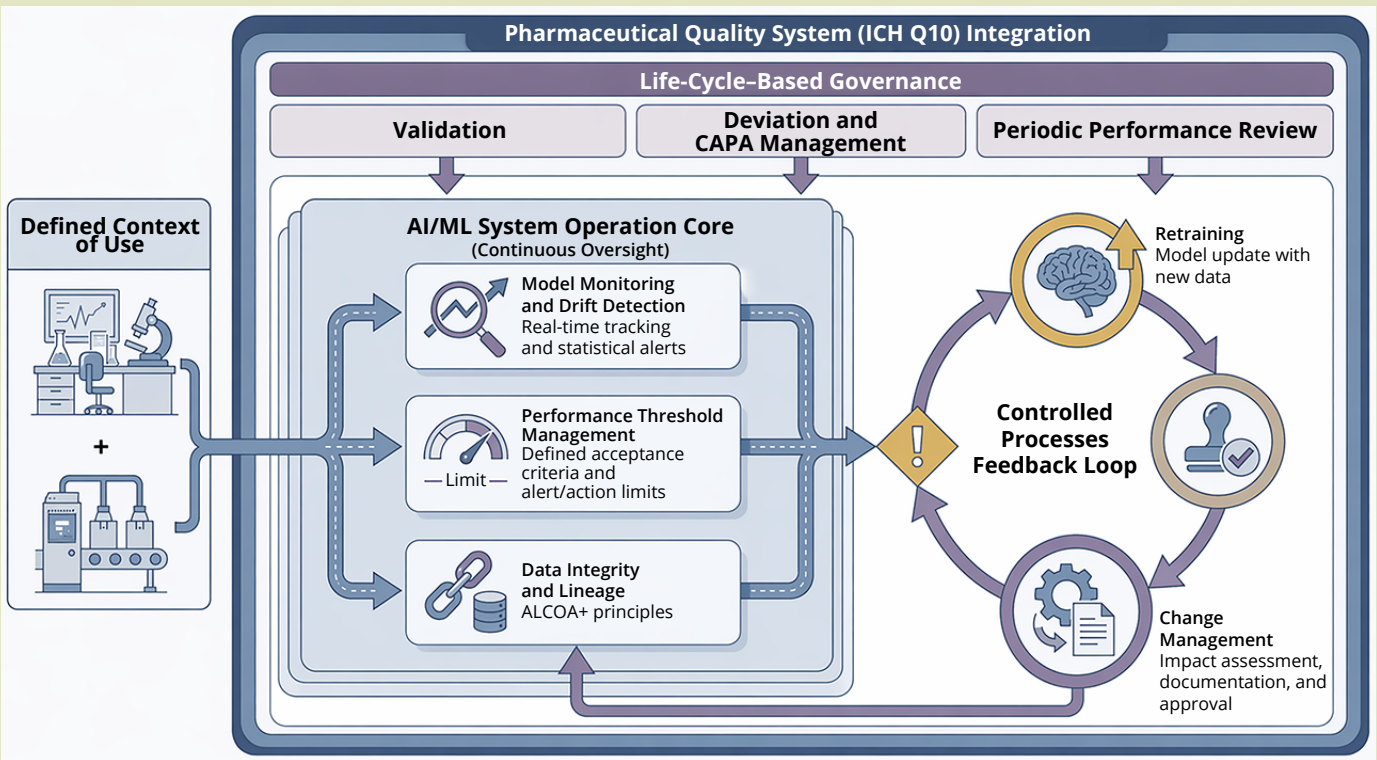
Figure 1: Framework for maintaining an algorithmic state of control for artificial intelligence (AI) and machine learning (ML) systems in good manufacturing practice (GMP) contexts. ALCOA+ = attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available; CAPA = corrective and preventative action; ICH = International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use



chromatography performance, resin-lifetime management, and impurity breakthrough behavior, in which process performance is governed by complex, multivariate interactions (**11, 12**). Such models can identify nonlinear relationships that are difficult to capture using traditional statistical approaches, thereby improving both process robustness and operational efficiency.

Manufacturing organizations are deploying AI-enabled analytics in operational environments, including predictive maintenance models for critical production equipment, anomaly detection within historical process data, and advanced deviation analysis tools to identify potential root causes across complex manufacturing datasets (**13**). In most current implementations, those systems function as decision-support tools rather than autonomous control systems, reflecting both the current level of technological maturity and regulatory caution as organizations prioritize human oversight in GMP-relevant decision-making.

In practice, the ease of adopting AI varies across the biopharmaceutical life cycle. Development-stage process optimization, particularly in chromatography development, remains one of the most accessible entry points. High-throughput experimentation platforms combined with ML approaches such as Bayesian optimization or active learning can explore complex purification parameter spaces more efficiently than traditional experimental strategies can, accelerating process understanding.

By contrast, introducing AI into established commercial manufacturing environments presents greater challenges. Many production facilities continue to operate with fragmented data architectures spanning process historians, laboratory information management systems (LIMS), manufacturing execution systems (MES), and process analytical technology (PAT) platforms. Without well-structured, integrated data pipelines, ML models may struggle to deliver reliable predictions. Such integration challenges often become most visible during technology transfer, commercial process monitoring, or inspection readiness activities, where fragmented data environments limit the reliability of advanced analytics. As a result, the pace of adoption is determined less by algorithmic sophistication and more by data-infrastructure maturity, the extent of sensor deployment, and organizational readiness.

As those capabilities expand, a central challenge emerges. Although the technical ability to deploy ML models in manufacturing environments is advancing rapidly, governance frameworks that ensure such systems remain reliable, interpretable, and appropriately controlled throughout their operational life cycles are less clearly defined.

Although the technical ability to deploy ML models in manufacturing environments is **ADVANCING RAPIDLY,** governance frameworks that ensure such systems remain reliable, interpretable, and appropriately controlled throughout their operational life cycles are less clearly **DEFINED.**

Case Study: AI-Enabled Chromatography Breakthrough Prediction

The following case is a representative, composite scenario informed by published studies and industry experience. It illustrates both the operational value and governance challenges of AI deployment in GMP environments.

In a commercial monoclonal antibody (mAb) process, a ML model is developed to predict product breakthrough during protein A chromatography using inputs such as load density, flow rate, ultraviolet (UV) absorbance, and feed composition. The model is trained on historical manufacturing and development data, and it demonstrates strong predictive accuracy during initial validation. During early deployment, the model is used in a decision-support capacity, providing operators with real-time predictions of breakthrough risk to optimize column loading. That enables improved resin utilization and reduces the risk of product loss.

Over time, however, process conditions begin to evolve. Resin aging alters binding capacity, and variability in upstream feed composition introduces subtle shifts in process dynamics. Although those changes remain within the validated process design space, they affect the statistical relationships on which the model was trained. Such behavior has been documented in recent studies that applied ML to breakthrough prediction and resin-lifetime monitoring for protein A chromatography (**11, 12**).

Table 1: Key differences between traditional good manufacturing practice (GMP) systems and systems driven by artificial intelligence (AI) and machine learning (ML); CAPAs = corrective and preventative actions, CPV = continued process verification, GxP = good practice, PQS = pharmaceutical quality system

Dimension	Traditional GMP Systems	AI/ML-Enabled Systems
Context of use	Defined through process design and validation documentation	Explicitly defined, including intended use, GxP impact, decision criticality, and operational boundaries
System behavior	Deterministic and predictable	Data-driven, probabilistic, and potentially adaptive within defined limits
Control strategy	Fixed process parameters within validated ranges	Model-informed control strategies supported by defined performance boundaries and monitoring controls
Validation approach	Process validation life cycle (stages 1–3), including CPV	Life-cycle–based validation including model development, training dataset justification, performance evaluation, and ongoing verification
Monitoring strategy	CPV with ongoing monitoring, trending, and deviation detections	CPV complemented by continuous model-performance monitoring, including drift detection and predefined thresholds for action
Data governance and integrity	Structured, controlled datasets	Diverse datasets, with enforced data lineage, traceability, version control, and access governance
Change management	Triggered by explicit process or system changes	Includes controlled model retraining, revalidation, and formal change control linked to performance drift or data changes
Failure modes	Equipment malfunction and process deviations	Model drift, data shift, algorithm misprediction, and loss of model generalizability
Human oversight	Operator-driven decision-making	Risk-based human oversight, including human-in-the-loop or review-by-exception depending on GxP criticality
Regulatory focus	Maintenance of a validated state through life-cycle process validation	Maintenance of validated state with additional assurance of model fitness for intended use through life-cycle monitoring and control
Integration with PQS	Managed within established PQS processes	Fully integrated within PQS, including deviation management, CAPAs, change control, and periodic review of model performance

Without active monitoring, the model's predictions gradually become less accurate. Importantly, that degradation in capability may not immediately trigger traditional change control mechanisms because no explicit process change has occurred. Instead, it represents a shift in model performance driven by evolving data. If unmonitored, such degradation could ultimately affect batch disposition decisions or process parameter adjustments, thereby necessitating deviation investigation, model performance review, and potential revalidation within a PQS.

This case illustrates a core challenge of AI in GMP manufacturing: Maintaining confidence in model outputs requires continuous oversight, even when the underlying process remains in control.

Governance and Control of AI Systems in GMP Environments

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Building on this emerging regulatory convergence, the biopharmaceutical industry already possesses well-established frameworks for governing computerized systems within GMP environments. EU GMP Annex 11 provides a foundational life-cycle framework for computerized systems used in GMP environments, including expectations for validation, data integrity, and change management (**14**). Those principles remain directly applicable to AI implementations but require reinterpretation to address the dynamic behavior of ML models. Table 1 summarizes key differences between traditional and AI-enabled GMP systems, including implications for control strategy, validation, and monitoring.

Within this evolving paradigm, the FDA's CSA framework provides a practical mechanism for implementing life-cycle–based assurance to ensure that software used in production and quality systems remains fit for its intended use throughout its life cycle. The CSA framework emphasizes focusing assurance activities on functions that impact product quality, patient safety, or data integrity, while enabling more flexible, continuous validation approaches. Importantly, the guidance is applicable to advanced data analytics and ML tools used in GMP environments, signaling a broader regulatory shift from static validation toward life-cycle–based assurance of software performance.

Consistent with 21 CFR 211.22 (**15**) and reinforced in a recent FDA warning letter (**16**), all AI-generated outputs or recommendations that may affect product quality must undergo documented review and approval by the authorized quality unit, ensuring that human accountability remains the ultimate responsibility.

Industry organizations have also begun providing more specific guidance. The International Society for Pharmaceutical Engineering (ISPE) recently published the *GAMP Guide: Artificial Intelligence,* which extends established good automated-manufacturing practice (GAMP) principles to AI-enabled systems (**17**). The guide addresses life-cycle governance, model transparency, data management, and the importance of monitoring algorithm performance after deployment.

These frameworks suggest that the governance challenges associated with AI are not entirely new. Rather, AI introduces additional dimensions that must be addressed within an existing PQS. Accordingly, governance of AI systems shifts from validating static functionality to ensuring sustained reliability under evolving manufacturing conditions.

Maintaining a State of Algorithmic Control

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Building on this life-cycle–based regulatory paradigm, a critical distinction emerges between "static" and "dynamic" AI applications within GMP environments. *Static* models, once trained and deployed, behave similarly to traditional deterministic software systems and can often be governed using established validation approaches. By contrast, *dynamic* models, particularly those designed to learn from newly acquired data or to be periodically retrained, introduce the potential for algorithmic drift over time.

In current GMP practice, most AI models are implemented as static or periodically retrained systems, with updates handled through formal change control. Fully adaptive or continuously learning models remain uncommon in regulated manufacturing environments, although they are an anticipated development.

Within this context, the concept of a state of algorithmic control can be understood as a natural extension of the traditional GMP concept of state of control, as defined in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q10 guidance (**18**), in which processes must operate within defined parameters and consistently produce predictable quality outcomes. When applied to AI, the concept extends beyond process parameters to include the behaviors of the algorithms themselves.

Maintaining that state of control requires continuous monitoring of model performance and timely detection of any degradation in predictive accuracy, supported by established quality system mechanisms such as deviation management, change control, and periodic performance review. In practice, maintenance of control

may include predefined performance metrics (e.g., predictive error, classification accuracy, or process-specific deviation rates), statistically justified alert thresholds, and defined triggers for investigation when model outputs fall outside acceptable limits.

Several practical elements support this objective, including a clearly defined model context of use, monitoring systems capable of detecting performance drift, robust data governance practices, and defined procedures for model retraining and revalidation. None of those elements are unfamiliar in GMP environments; what changes is the level of persistence required. Algorithms demand ongoing oversight and periodic retraining, introducing life-cycle considerations that differ fundamentally from traditional deterministic software systems.

Inspection readiness for AI systems will depend on an organization's ability to demonstrate not only that a model was appropriately validated at deployment, but that its performance remains continuously verified under real manufacturing conditions. This shift changes the inspection focus from consideration of static validation evidence to assurance of dynamic system performance, requiring both inspectors and manufacturers to evaluate how control is maintained over time rather than at a single timepoint.

In this sense, maintaining a state of algorithmic control should be regarded not merely as an extension of GMP expectations, but as a necessary condition for demonstrating control in data-driven manufacturing environments.

Implications for the Biopharmaceutical Industry

As AI is increasingly explored in GMP manufacturing, both biopharmaceutical companies and their manufacturing partners will need to adapt their governance frameworks accordingly. The challenge is not simply technical implementation; it also involves ensuring that algorithmic systems operate within the disciplined control structures required in regulated manufacturing environments.

Quality systems will need to evolve to accommodate ongoing model monitoring and life-cycle management. Manufacturing organizations must define clear boundaries for where AI-enabled decision support can be applied safely and effectively. Such governance decisions will increasingly influence day-to-day operational practice. Regulators, meanwhile, will continue refining expectations as industry experience with these technologies expands and real-world implementation provides additional regulatory insight.

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AI has the potential to strengthen process understanding, improve operational efficiency, and enhance manufacturing robustness across the biopharmaceutical sector. Realizing such benefits will depend on the ability of organizations to integrate algorithmic technologies into established quality and regulatory frameworks.

AI does not simply introduce new tools into GMP manufacturing; it reshapes how control must be demonstrated. In environments where algorithmic systems influence process decisions, maintaining control requires continuous assurance of both process performance and model behavior. As AI/ML technologies become more deeply embedded in manufacturing operations, the ability to demonstrate an algorithmic state of control will transition from an advanced capability to a fundamental expectation of GMP compliance. In this context, AI will reshape not only how pharmaceutical processes are optimized, but also how they are governed within a PQS.

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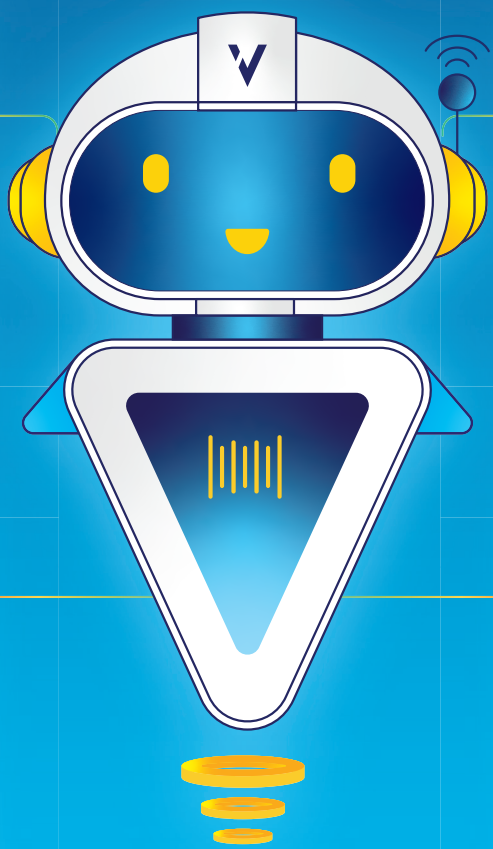

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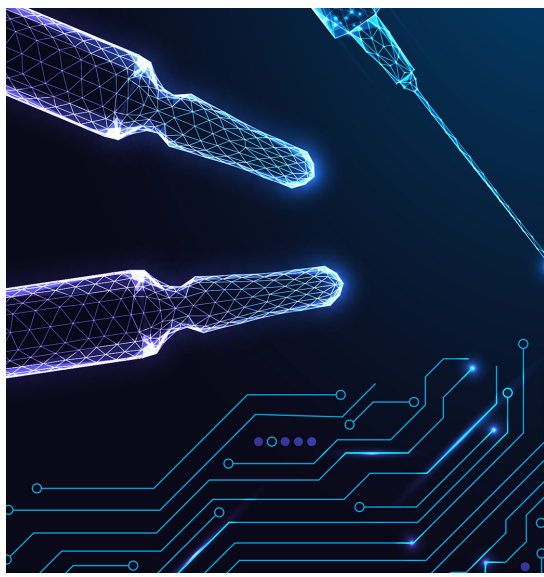

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Artificial intelligence (AI) is rapidly transitioning from exploratory analytics to operational deployment within biomanufacturing. Across the industry, data-driven technologies are being applied to enhance process understanding, improve operational efficiency, and strengthen manufacturing robustness. As those capabilities move closer to influencing decision-making within good manufacturing practice (GMP) environments, the central question is no longer whether AI can be used in manufacturing, but instead how it can be governed within established regulatory frameworks.

The pharmaceutical industry is beguiled with the promise of artificial intelligence (AI), but industry insiders reveal a significant disparity between executive vision and operational readiness. Although AI adoption is progressing across the sector, it remains highly uneven; current success is largely limited to speeding up documentation and compliance. The dreams of autonomous factories are still some way off.

BioPhorum, a collaborative industry network, has consolidated benchmarking data across its members (collected throughout 2025) to analyze themes, use cases, and limitations of AI tools in the pharmaceutical industry. We found the following:

- AI was live and embedded in only four of the 30 use cases recorded. Those use cases sat within quality, information-technology (IT), and data-science functions.
- 13 out of 30 use cases were still in the pilot or development phase, whereas 12 were still under consideration.
- Within drug development, three out of 21 responding organizations noted that they were scaling pilots successfully, and none had fully embedded workflows.
- Members within advanced therapies showed the slowest uptake of AI, with no use cases live or in the pilot stage.

So where is AI actually adding value? AI is being adopted primarily for deviation management, documentation review,

compliance checking, and complaints management. Organizations are finding quick wins by deploying AI to assist with standard operating procedure (SOP) authoring, audit-trail reviews, and annual product-quality reviews. In one notable instance, AI was used to reduce manufacturing execution system (MES) source-code review time from 16 hours to under a single hour.

Beyond paperwork, more advanced applications are beginning to emerge in predictive analytics and in silico modeling. Predictive analytics are now actively optimizing drug yields and acting as early warning systems on the factory floor by detecting abnormal states in bioreactors before costly failures occur. AI is also shifting trial-and-error experimentation out of physical laboratories and into virtual simulations, acting as an advanced assistant that simplifies data workflows and drastically accelerates the scientific test and learning cycle.

However, broad transformative gains have yet to progress because of a data problem. Data readiness — specifically, questions of data access, availability, formatting, and lineage — has emerged as the single largest barrier to AI deployment across the industry. Before organizations can reap the rewards of such technologies, they must spend years cleaning and connecting fragmented, inaccessible datasets. Currently, over half of surveyed organizations admit that they have not harmonized their unstructured data, relying instead on manual extraction and transformation. Without clean, structured data as a precursor, meaningful validation of advanced AI models is simply impossible.

Without clean, structured data as a precursor, meaningful validation of advanced AI models is simply **IMPOSSIBLE.**

Despite such hurdles, many pharmaceutical companies are not buying off-the-shelf AI software. BioPhorum's benchmarking shows a distinct preference across the industry for building AI capabilities internally rather than purchasing commercial tools. This trend is perfectly illustrated in quality operations: Out of 19 recently implemented tools, 12 were developed entirely in house, seven were codeveloped with a vendor, and none were purchased directly as off-the-shelf solutions. That build preference is driven by high data sensitivity, the need to encode bespoke proprietary processes, and a lack of maturity among commercial vendor offerings. Greater maturity is needed to meet strict compliance needs in a highly regulated industry.

Regulation is another key barrier to AI progress. For decades, the pharmaceutical industry has relied on strict validation processes to guarantee safety. Those processes, built for traditional software, are designed to be perfectly predictable. But modern AI isn't traditional software; it is designed to learn, adapt,

and shift its behavior based on new data. The industry's current rulebooks simply are not built to handle tools that constantly evolve. Right now, regulatory expectations for those models remain clouded at best, leaving companies guessing how to formally prove that an AI tool will not drift off course.

Ultimately, the vision of fully agentic and autonomous systems that independently manage complex workflows is still a long way off. Across all industry groups evaluating such technologies, there is consensus that AI tools must be audit-ready and compliant by design. AI models lack a true semantic understanding of manufacturing intent or clinical context, and thus human-in-the-loop oversight remains essential for all scientific and operational decision-making.

Although the pharmaceutical industry is finding ways to build its own tools for administrative wins and early-warning alerts, organizations are still wrestling with the unglamorous groundwork. Until such deep-rooted data issues are fully rectified and regulators write a new playbook for adaptive technology, the sector cannot use the technology to drive real, transformative value. We may be in the age of AI, but the human expert is not leaving.

About the Author

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