Artificial Intelligence

Risks and Rewards of Innovative Technologies

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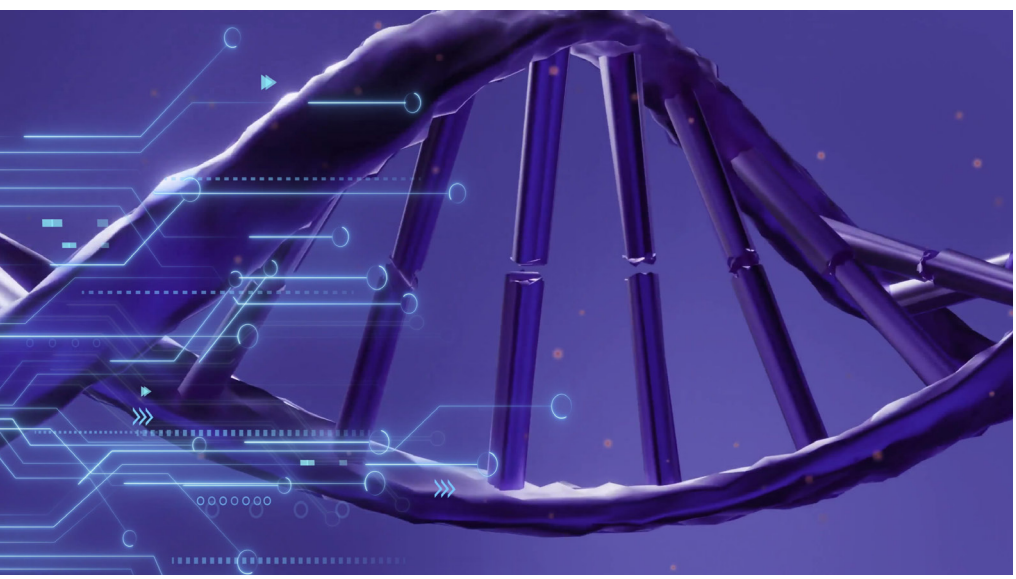

Tools and technologies incorporating artificial intelligence (AI) are becoming increasingly prevalent in biomanufacturing, accelerating timelines, reducing human errors, and enabling new insights during discovery. When applied properly, AI technologies can provide immense benefits to the industry. In this latest BPI eBook, industry professionals discuss the risks and benefits of AI throughout biomanufacturing.

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Generative AI in Drug Development?

Don't Forget the Cybersecurity Risks

Anand Naik

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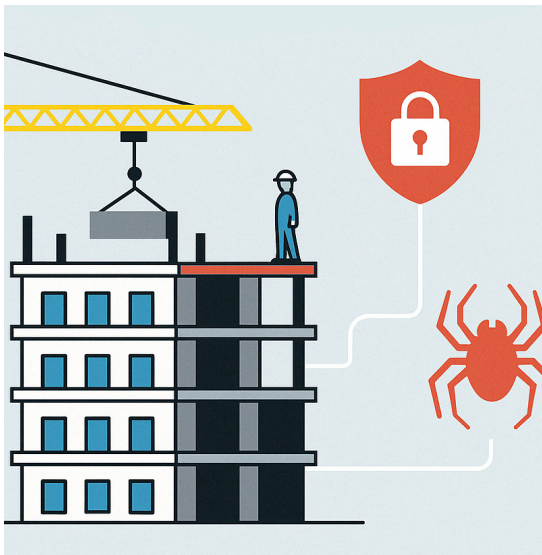

Imagine a skyscraper under construction: Each floor represents a breakthrough in drug discovery, clinical trials, and/or manufacturing processes. Generative artificial intelligence (GenAI) would be a construction crane, lifting and positioning each piece and accelerating the pace of work in the biopharmaceutical industry. Although the crane can help to build such a structure, its power also introduces significant risk; if not properly controlled, it can damage the building. In the biopharmaceutical industry, such damage could risk sensitive intellectual property (IP), regulatory compliance, and patient safety.

The biopharmaceutical industry is on the verge of a monumental transformation driven by the power of GenAI. With the potential to revolutionize drug discovery, optimize clinical trials, and streamline manufacturing processes, it promises to change how the pharmaceutical sector operates. By 2025, the global market for AI in biopharmaceuticals is projected to exceed US$3.8 billion, with generative models driving much of that growth (**1**). However, amid the rapid progress, one critical consideration is often overlooked: cybersecurity. Although GenAI offers innovative capabilities (e.g., predicting molecular structures, generating novel compounds, and orchestrating clinical trials), it also introduces new cybervulnerabilities. The stakes are high for an industry in which a single molecule's formula represents years of research and billions in potential revenue.

GenAI Reshapes Cybersecurity

As biopharmaceutical companies are adopting GenAI, the cybersecurity landscape is undergoing a fundamental transformation. Traditional cybersecurity — meant to protect databases, networks, and endpoints — is insufficient for such a venture because GenAI introduces several new and complex components that must be secured.

New Angles of Attack: GenAI expands attack surfaces because it changes how drugs are discovered and manufactured. Several key areas now require enhanced security protocols.

Training Data Repositories: Large datasets containing proprietary molecular structures, biological pathways, and clinical outcomes now are centralized and accessible to train AI models, creating high-value targets for attackers.

Model Architecture: The algorithms powering generative models represent valuable IP themselves, often containing embedded knowledge from training on proprietary datasets.

Inference Endpoints: Application programming interfaces (APIs), through which researchers interact with models, become new entry points for attackers seeking to manipulate outputs or extract training data.

Prompt-Engineering Systems: The increasingly complex prompts used to guide GenAI systems can contain confidential research directions or proprietary methodologies. The difficulty lies in how AI systems are designed to generate new information based on patterns in their training data. That fundamental capability becomes a vulnerability when threat actors target the extraction capabilities of these systems, potentially leaking sensitive data or altering the AI's output for malicious purposes.

Biopharmaceutical research and development (R&D) presents challenges that amplify GenAI security risks.

Collaborative Development: Drug discovery often involves multiple partners, contract research organizations (CROs), and academic institutions sharing access to GenAI platforms, expanding the potential for unauthorized access.

Regulatory Documentation: GenAI tools used for regulatory submission preparation might incorporate or expose sensitive data subject to strict regulations.

High-Value Targets: Nation-state actors and business competitors have strong incentives to target GenAI systems containing valuable IP or competitive intelligence about research directions.

Legacy-System Integration: Many pharmaceutical companies are integrating cutting-edge GenAI capabilities with decades-old laboratory systems that were not designed with modern cybersecurity principles. The US Department of Health and Human Services (HHS) Health Sector Cybersecurity Coordination Center (HC3) states that the healthcare and pharmaceutical sectors continue to be among the most susceptible industries to ransomware and IP theft (**2**).

The Current Threat Landscape

Theoretical concerns about GenAI security in biopharmaceuticals are materializing rapidly into concrete threats. Several vulnerability categories have emerged as particularly relevant.

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Model poisoning involves manipulation of training data or fine-tuning processes to compromise model outputs. Some examples include

- introducing subtle biases that cause models to deprioritize promising molecular structures
- embedding "backdoors" that generate flawed chemical compounds when specific triggers are present
- corrupting training data to make models produce suboptimal or even dangerous drug candidates.

In 2024, researchers demonstrated how a poisoned generative chemistry model could be induced to design compounds with hidden toxicity profiles that would not be detected in standard safety screenings (**3**).

Prompt-injection attacks craft inputs that override safety mechanisms or extract confidential information. Such attacks can be direct or indirect, and they can involve manipulation of models. Malicious prompts can be designed to extract proprietary molecular structures from the model's training data. Seemingly innocuous research queries that gradually build context can lead to disclosure of confidential information. And manipulation of a model can make it generate outputs in formats that bypass security monitoring tools.

A notable incident occurred when a pharmaceutical company's internal GenAI system was manipulated through carefully crafted prompts to reveal aspects of a patent-pending compound structure. The organization discovered the breach only after finding its research approach described in a competitor's patent filing.

Data Leakage Through Memorization: Large language models (LLMs) and other such systems often memorize portions of their training data, which creates risks of inadvertent disclosure such as

- exact sequences from proprietary datasets appearing in model outputs
- statistical inference attacks that enable reconstruction of private training examples
- extraction of high-value proprietary relationships between biological targets and compounds.

Supply-Chain Vulnerabilities: The supply chain introduces multiple points of vulnerability. For instance, pretrained base models might contain undisclosed weaknesses, and third-party model-optimization services could expose proprietary fine-tuning data. API providers might have inadequate security controls despite needing to handle sensitive queries. And computer infrastructure could be compromised, particularly when using shared resources.

Develop **GUARDRAILS** around LLM prompts to prevent prompt-injection attacks. Such measures include input sanitization, limited prompt length, and disabling model memory in **HIGH-RISK** contexts.

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Security Blind Spots

As pharmaceutical companies integrate GenAI tools into their operations, new security blind spots emerge, particularly at integration points with third-party systems and legacy infrastructure. Organizations. often integrate GenAI systems into their existing information-technology (IT) frameworks with little regard for the new technologies' security requirements. In many cases, GenAI is simply "bolted on" to outdated legacy systems, opening major gaps in security.

Legacy-system incompatibility occurs when cutting-edge GenAI systems are integrated with old on-premises databases and clinical-trial management systems (CTMS). When those tools are added to existing systems without re-engineering security architecture, the incompatibility creates unmonitored entry points that can be exploited by cybercriminals.

Third-party risk is another blind spot. Many pharmaceutical organizations rely on external AI vendors for data analytics, drug discovery, and/or chemical modeling. However, most third-party vendors do not have mature cybersecurity practices in place, making those platforms prime targets for hackers. Without secure API gateways and adequate audit logging, such integrations are highly vulnerable.

The **lack of model governance** compounds the previously stated issues. Traditional IT systems rely on strong audit trails and access controls to track user activity and data flow. However, it is much harder to trace how GenAI models (especially black-box LLMs) reach their conclusions or which data they were exposed to. Without clear governance protocols, tampering and unauthorized access are difficult to detect.

Securing GenAI-Enabled Drug Development

To counter growing cybersecurity risks without stifling innovation, pharmaceutical companies must adopt multilayered cybersecurity approaches. Doing so requires focusing on several key practices that will help to mitigate GenAI risks.

Access Controls and Role-Based Permissions: Restrict access to GenAI tools based on user roles within the company. Sensitive data, such as patient records and proprietary research, should not be accessible to people involved in early stage discovery. Use multifactor authentication (MFA) and least-privilege principles to minimize unauthorized access.

Data Segmentation and Masking: It is crucial to segregate training- and inference-data environments to prevent sensitive information from being exposed during model training

or prompt processing. Implement tokenization or data-masking techniques to safeguard proprietary data, such as patient-level genomic information.

Secure Model-Training Pipelines: Before GenAI models are implemented, companies must verify the authenticity of training data. Encrypt data both in transit and at rest and use strict verification and provenance tracking to detect unauthorized tampering of training datasets.

Prompt Security and Input Validation: Develop guardrails around LLM prompts to prevent prompt-injection attacks. Such measures include input sanitization, limited prompt length, and disabling model memory in high-risk contexts. Use content-filtering and moderation tools to identify suspicious queries.

Third-Party Risk Management: Conduct extensive vetting of third-party AI vendors and API providers. Ensure that they have cybersecurity certifications and require regular audits of their security practices to ensure compliance with industry standards.

Model Explainability and Auditing: Implement LLMs with explainability capabilities and track output provenance. Record all model interactions, ensuring that each session can be audited for security and compliance

Incident Response and AI-Specific Playbooks: Develop and routinely test incident-response playbooks specific to GenAI threats. Such threats include model hijacking, memory data leaks, and prompt abuse. The playbooks also must include rapid shutdown protocols, data-breach notification procedures, and regulatory reporting protocols.

Supply-Chain Security: Secure the entire GenAI supply chain, from data ingestion to model deployment and monitoring. That includes ensuring the integrity of datasets, containers, model weights, and API endpoints.

Culture of Role Security as a Cross-Functional Imperative

Securing GenAI systems is no longer the sole responsibility of the IT department. It has become a company-wide imperative that requires collaboration among R&D teams, cybersecurity experts, compliance officers, and data scientists. Cross-functional oversight committees should be established to define governance policies for GenAI security and ensure that they are followed throughout all departments.

Employee cybersecurity training is equally critical. Everyone involved in handling GenAI tools, from laboratory scientists to regulatory writers, must be equipped with awareness about

PROACTIVELY INVESTING in security and compliance frameworks today can yield significant long-term business and regulatory advantages.

cybersecurity threats such as phishing, prompt injection, and accidental data sharing. Empowering staff to recognize and report potential risks will help to strengthen an organization's first line of defense.

Regulatory Momentum on the Horizon

As pharmaceutical companies learn how to secure GenAI systems, regulatory bodies are catching up. The US Food and Drug Administration (FDA), through its *AI/ML Action Plan*, has indicated its intent to develop a framework to ensure the quality, safety, and efficacy of AI tools used in regulated processes (**4**). Similarly, the National Institute of Standards and Technology (NIST) has published guidelines on AI risk management, with an emphasis on robustness, explainability, and security (**5**).

Moreover, the US Congress is debating new data-protection laws related to AI, which will significantly impact how pharmaceutical companies manage and process data within GenAI systems. Existing regulations, such as the Health Insurance Portability and Accountability Act (HIPAA) and 21 *Code of Federal Regulations* (CFR) Part 11, will need to extend their scopes to include AI-generated content and ensure compliant AI use in regulated environments.

Companies that adopt a "wait-and-see" approach might be forced to play catch-up once regulations are finalized. Proactively investing in security and compliance frameworks today can yield significant long-term business and regulatory advantages.

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From Algorithms to Antibodies

Artificial Intelligence as the Engine of Smart Biomanufacturing

Jason Beckwith, Stephen Goldrick, William Nixon, and Stavros Kourtzidis

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The biomanufacturing landscape is undergoing a profound digital transformation, catalyzed by the integration of artificial intelligence (AI) technologies throughout development and production workflows. The shift is not merely additive; AI is enabling capabilities that exceed the reach of traditional statistical methods and heuristic-driven control systems. From high-resolution protein modeling to adaptive control of continuous purification systems, AI now can play a central role in precision bioprocessing. However, realizing its potential requires not only technological adoption, but also workforce reengineering, robust data infrastructure, and new validation paradigms that are suitable for good practice (GxP) environments.

Classification and Technical Capabilities

AI in biomanufacturing comprises a diverse portfolio of algorithmic tools, each designed to address specific operational and analytical challenges throughout product life cycles. Such technologies have different data requirements, interpretability, and maturity of deployment but together can form the backbone of digital transformation in bioprocessing.

Supervised machine learning (ML) algorithms such as random forests, gradient-boosted trees, and support vector machines (SVMs) can predict product titers, critical process parameters (CPPs), and quality outcomes from structured sensor and batch data. Such models rely on labeled datasets and are well-suited for environments in which input–output relationships are stable and repeatable. They support fault detection, yield forecasting, and predictive maintenance routines for both upstream and downstream processes.

Deep Learning: For complex and/or nonlinear tasks, deep-learning architectures, particularly convolutional (CNNs) and recurrent neural networks (RNNs), are applied increasingly. CNNs excel in image-based applications (e.g., cell-morphology analysis

and in-process microscopy), whereas RNNs (such as models based on long short-term memory, LSTM) are used in time-series applications — e.g., process analytical technology (PAT) signal interpretation and fermentation yield prediction. Such models can extract patterns from high-dimensional, noisy data, enabling detection of subtle process deviations in real time.

Reinforcement learning (RL) is gaining traction in upstream control systems, especially for dynamic optimization of fed-batch and perfusion bioreactors. In these scenarios, an RL agent iteratively learns control policies through interaction with the bioprocess environment, either through simulations or real-time experimentation. Unlike traditional proportional–integral–derivative (PID) or model-predictive control (MPC) systems, RL can balance multiobjective trade-offs, such as maximizing cell viability while minimizing by-product accumulation. That makes RL highly suitable for adaptive control in complex, variable bioprocessing.

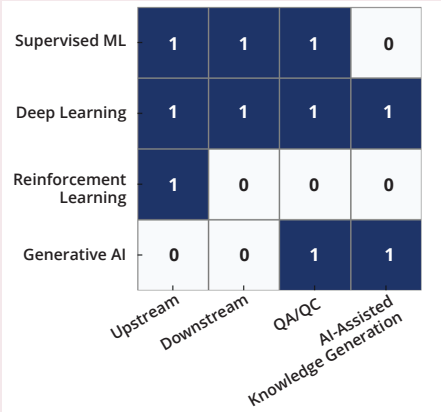
Hybrid models combine mechanistic process knowledge with data-driven learning to create digital twins, virtual replicas of a biomanufacturing system that are capable of simulating and optimizing performance under varied conditions. Such models leverage physical laws to ensure interpretability while using neural networks to capture unmodeled phenomena, such as equipment fouling or raw-material effects. Applications include real-time control of perfusion bioreactors and optimization of chromatography elution profiles.

Generative AI can be applied to knowledge-management functions that support bioprocess research and development (R&D) and compliance. Such models are used for automated literature mining, protocol synthesis, and documents for regulatory submissions. Advanced frameworks such as retrieval-augmented generation (RAG) combine large language model (LLM) reasoning with structured database access, enabling applications such as real-time hypothesis generation and multiomics interpretation. Although still in early stages, those tools are accelerating the "learn" phase of design–build–test–learn (DBTL) workflows.

Mapping AI to Biomanufacturing Stages

AI application differs significantly throughout biomanufacturing life cycles. To visualize that, we analyzed each technology's implementation across four functional domains: upstream processing, downstream purification, quality assurance/control (QA/QC), and AI-assisted knowledge generation. Figure 1 maps AI types to their application areas; Figure 2 quantifies the number of distinct AI technologies that might be used per biomanufacturing stage.

Figure 1: Technology-function matrix highlighting alignment of specific artificial-intelligence (AI) types with biomanufacturing processes; a 1 denotes functionality within a process, whereas a 0 reflects no functionality. ML = machine learning, QA = quality assurance, QC = quality control.



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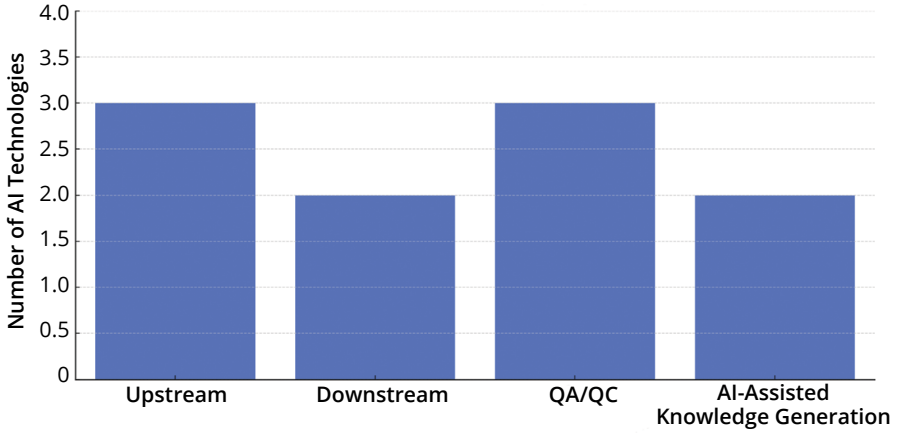
Upstream and QA/QC domains currently lead in AI adoption, driven by demand for real-time prediction, anomaly detection, and yield stabilization. By contrast, downstream processing and knowledge synthesis represent growth frontiers, in which advanced techniques such as hybrid modeling and generative AI are showing significant promise. Notably, AI-assisted knowledge generation, driven by LLMs and RAG, is emerging as a discrete and impactful area, supporting scientific-literature mining, protocol generation, and regulatory text synthesis. That segmentation helps to clarify where AI technologies currently are delivering operational value and where future growth is expected. Such mapping can serve as a foundation for detailed process-stage analyses.

Figure 2: Distribution of artificial intelligence (AI) tools in each major stage of biomanufacturing; QA = quality assurance, QC = quality control



Integration Throughout Biomanufacturing

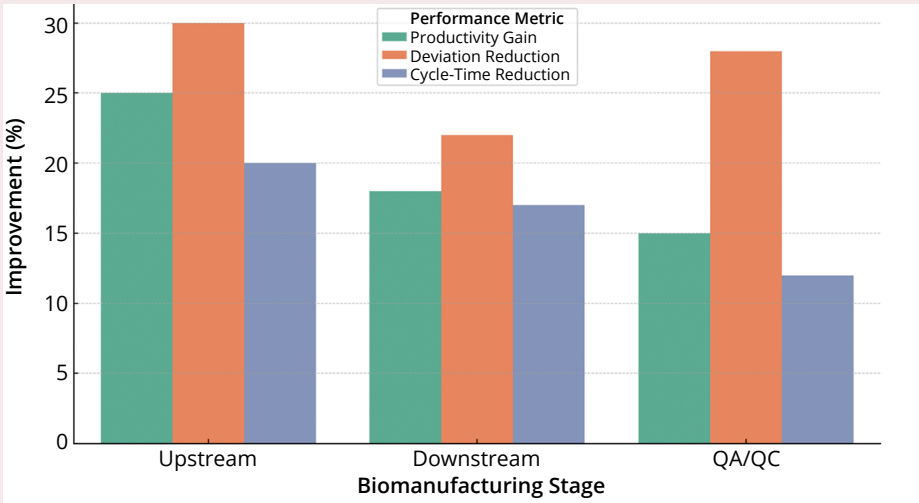
AI application in biomanufacturing is reshaping process control, optimization, and QA. By embedding AI capabilities into upstream, downstream, and release operations, organizations can achieve step-changes in efficiency, predictability, and adaptive decision-making.

In **upstream operations,** AI technologies can accelerate strain optimization, feed-strategy refinement, and dynamic culture control. Active learning frameworks designed to iteratively identify the most informative experiments now are used to reduce the volume of wet-laboratory testing and compress development timelines. Such models prioritize conditions with the highest predicted variance or uncertainty, enabling informed allocation of laboratory resources. Additionally, transfer learning can be used to adapt pretrained models across related cell lines, culture formats, and media formulations. That enables organizations to build scalable, platform-compatible models that generalize across products and reduce the need for process redevelopment.

In **downstream processing,** ML algorithms are improving precision and robustness of ultrafiltration/diafiltration (UF/DF), tangential-flow filtration (TFF), and continuous chromatography. Models trained on multivariate PAT data — e.g., transmembrane

pressure, conductivity, and ultraviolet (UV) absorbance — enable real-time adjustment of flow rates and buffer compositions. That reduces protein loss and mitigates variability in product concentration and purity. Fault-classification models also are applied to identify early indicators of fouling, channeling, or breakthrough events. Such predictive systems support proactive maintenance scheduling and reduce unscheduled downtime, improving equipment use and batch reliability. Integration with supervisory control and data acquisition (SCADA) platforms enables automated feedback control based on AI model recommendations.

Figure 3: Impact of artificial intelligence (AI) integration throughout biomanufacturing stages; QA = quality assurance, QC = quality control



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QA and Product Release: AI can augment conventional statistical process-monitoring (SPM) techniques. Deep-learning–based SPM systems detect subtle shifts in high-dimensional datasets, which can be missed by traditional methods such as Shewhart or cumulative-sum (CUSUM) charts. Such models improve fault-detection sensitivity and enable early interventions, reducing the risk of batch rework and rejection.

To complement the qualitative review of AI integration across biomanufacturing, we present indicative quantitative gains drawn from reported industry benchmarks and pilot deployments. Those include metrics such as productivity improvement, deviation reduction, and cycle-time compression across upstream, downstream, and QA/QC stages. Figure 3 illustrates quantified effects of AI technologies throughout major biomanufacturing domains. AI-enabled systems have demonstrated the highest gains in upstream processing, where model-guided optimization of feed strategies and culture conditions has yielded substantial improvements. Downstream and QA/QC functions are showing measurable benefits, particularly in anomaly detection, predictive maintenance, and accelerated release decisions.

The data underscore AI's value as a cross-functional enabler of performance, stability, and speed. Further downstream, generative models are being explored to predict critical quality attributes (CQAs) based on in-process and upstream data. Predictive quality models can reduce destructive sampling and enable real-time

release testing (RTRT) by forecasting final-product specifications before analytical assays are complete. Although still in early use, such models represent a key enabler of adaptive quality systems underpinned by AI.

Case Study: AI-Driven Yield Optimization

Amgen, a leading biotechnology company, has been at the forefront of AI integration in commercial-scale biomanufacturing. A notable initiative within its monoclonal-antibody (mAb) production platform involved use of advanced ML models to improve bioreactor performance, enhance process robustness, and maximize product yield. The program reflects a significant shift from reactive process management to proactive, data-driven control.

The company began by aggregating and harmonizing historical process data from <100 full-scale production batches. Those datasets included high-frequency time-series data from PAT instruments, environmental variables, and laboratory-based quality assays. Critical process parameters (CPPs) and CQAs were selected as target variables for prediction, forming the foundation of the model-training datasets.

Amgen's data-science team used a suite of ML models that focused on ensemble methods such as random forest approaches and tools used in XGBoost software. Such models demonstrated superior performance in capturing nonlinear relationships and interactions between process inputs and outputs. The selected models were trained to predict yield-affecting deviations, shifts in viability, and early indications of CQA drifts. Once validated, the models were embedded into a digital monitoring framework and connected to real-time data feeds from a manufacturing execution system (MES).

The results of that implementation were multifaceted. First, the predictive models enabled early detection of bioreactor anomalies, including suboptimal feed conditions and potential contamination events. In one example, the system flagged a trajectory of rising lactate levels six hours earlier than manual trend recognition could, enabling prompt corrective actions. Second, in silico feedback loops were established, allowing model predictions to guide operational decisions, such as feed-rate adjustments and temperature tuning, during the production run itself.

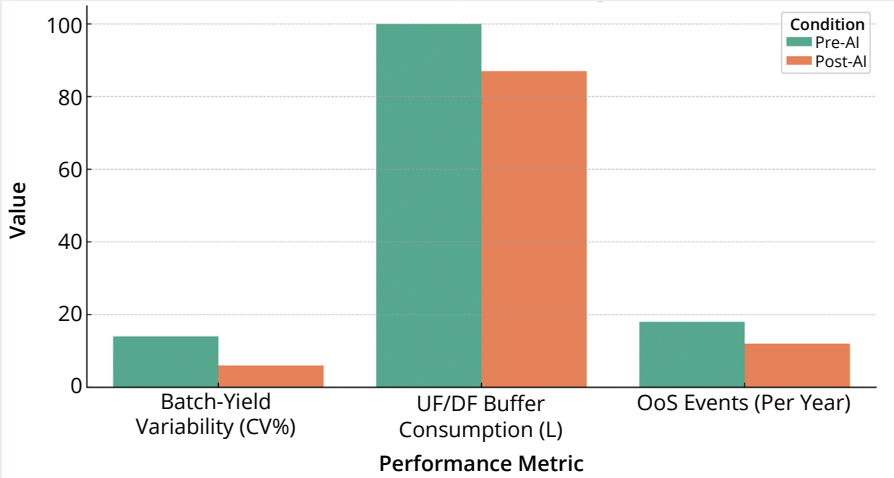
Quantitatively, the intervention led to a documented >30% reduction in process deviations and out-of-specification events. Furthermore, yield variability was reduced significantly, with coefficient of variation across production runs dropping from ≈14% to <6%. The economic implications were substantial, including

AI is no longer just an **EMERGING** concept in biomanufacturing; it is becoming a **FOUNDATIONAL** capability.

increased throughput and reduced scrap rates, outcomes critical in high-value biologic manufacturing.

Amgen's approach is particularly notable for its integration of AI within a regulated manufacturing environment. The models underwent rigorous performance qualification and were aligned with internal GxP validation standards. Continuous model retraining was enabled using secure version-controlled pipelines, and interpretability tools (e.g., SHapley Additive exPlanations, SHAPs) were used to ensure that outputs could be audited and reviewed by QA professionals. The Amgen case provides strong empirical support that AI can improve biomanufacturing efficiency, stability, and regulatory confidence when implemented through a robust data infrastructure, cross-functional collaboration, and a validation-first mindset. Quantifiable gains from such initiatives are evident among other leading manufacturers, as well. Implementation of ML-driven control frameworks resulted in lower variability, reduced material use, and fewer out-of-specification events, validating AI's value in regulated production environments (Figure 4).

Figure 4: Comparative performance metrics before and after artificial intelligence (AI) implementation in commercial biomanufacturing (adapted from **1, 2**); CV = coefficient of variation, OoS = out of specification, UF/DF = ultrafiltration and diafiltration



Talent and Workforce Transformation

The deployment of AI in biomanufacturing necessitates a fundamental rethinking of workforce roles and required competencies. Traditional manufacturing roles have been defined by manual control, SOP execution, and empirical troubleshooting. Increasingly, those are augmented or replaced by roles focused on data engineering, model development, and algorithmic oversight. That shift demands new cross-functional talent to bridge biotechnology, automation, software engineering, and data science. Key emerging roles include *AI-operations specialists,* who maintain the integrity, monitoring, and validation of applied models within regulated environments. Bioprocess data scientists are now integral to process-development teams, for which they are tasked with building models that link process parameters to product quality attributes. *Domain-fluent ML engineers,* those with training in both

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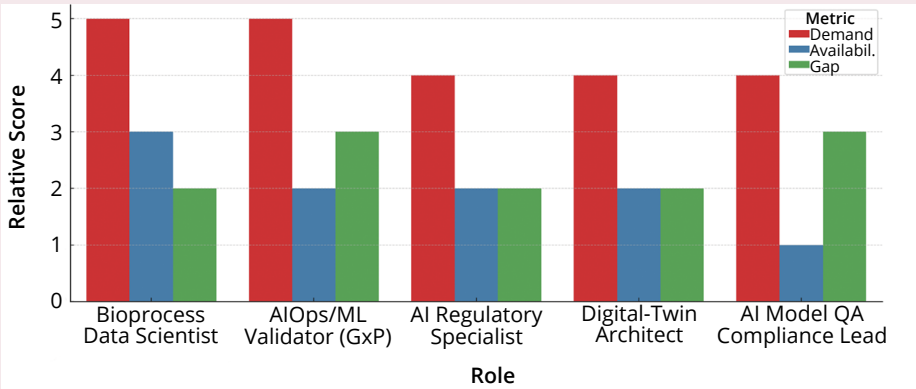
AI and good manufacturing practices (GMPs), are especially scarce as they become critical to scaling AI adoption beyond pilot programs.

Upskilling initiatives are crucial to enable meaningful engagement with AI systems. Such upskilling includes training in statistical thinking, Python-based toolkits (e.g., SciKit-learn and TensorFlow), and validation frameworks (e.g., good automated manufacturing practice 5, GAMP 5, with AI extensions). Companies are adopting "AI-fluent" curricula in collaboration with academic institutions to train the next generation of scientists in those skills.

Figure 5: Comparative analysis of demand, availability, and capability gaps across emerging roles related to artificial intelligence (AI) in biomanufacturing; AIOps = AI operations, GxP = good practice, ML = machine learning, QA = quality assurance



Furthermore, regulatory-engagement skills are increasingly important. Quality professionals now must assess the explainability and life-cycle management of AI models. Concepts such as model drift, algorithmic bias, and retraining intervals are entering the lexicon of GxP audits, requiring alignment among information technology (IT), QA, and biomanufacturing teams.

Figure 5 highlights significant capability deficits remaining across key AI-enabling roles, including AI operations/ML validators, digital twin architects, and regulatory specialists. Closing those gaps requires a combination of targeted talent acquisition, interdisciplinary upskilling, and strategic partnerships between academia and industry to build a future-ready biomanufacturing workforce.

Regulatory, Validation, and Quantitative Performance Considerations

Safe and sustainable implementation of AI in biomanufacturing requires rigorous validation and regulatory alignment. Unlike traditional static-control algorithms, AI models are adaptive by design: They learn over time, respond to new data, and evolve in performance. Such adaptability introduces new compliance challenges around model drift, algorithmic bias, and explainability that must be addressed within regulated biopharmaceutical environments.

To meet such demands, AI systems must adhere to established and emerging frameworks, including GAMP 5, the US Food and Drug Administration's (FDA's) computer software assurance (CSA)

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guidance, and the European Medicines Agency's (EMA's) evolving position on AI/ML in medicinal-product development. Such frameworks emphasize transparency, traceability, and life-cycle control as prerequisites for AI use in GxP environments.

Key Components of a Validated AI Life Cycle: A robust validation strategy for AI in bioprocessing typically should includes

- initial performance qualification to establish baseline reliability, using methods such as *k*-fold cross-validation, receiver operating characteristic–area under curve (ROC-AUC), and residual error analyses
- continuous performance monitoring, enabled through version-controlled pipelines and trigger-based retraining thresholds to mitigate drift and ensure model stability
- explainability frameworks, such as SHAP or local interpretable model-agnostic explanations (LIME), to generate interpretable model outputs that support QA reviews and regulatory audits.

Those components can help to bridge the gap between black-box algorithm outputs and the transparency required for QA and regulatory submission.

Quantifiable Performance Benefits: Early adopters have demonstrated operational and financial benefits of well-validated AI implementations in GMP environments. Reported benefits include

- up to 35% reduction in downstream process variability, driven by real-time analytics and predictive process control
- 25–40% decrease in material use in UF/DF operations through AI-optimized buffer consumption and flow-rate adjustment
- 6–10% increase in average bioreactor yield enabled by ML-guided feed-strategy refinement and early deviation detection.

Those outcomes highlight the importance of viewing AI not merely as a data-science tool, but also as a validated, auditable, and performance-enhancing component of biomanufacturing control systems.

Future-Readiness: Challenges and Mitigation Strategies

Although AI has demonstrated measurable value in biomanufacturing, its large-scale adoption remains constrained by technical, organizational, and regulatory barriers. Overcoming these challenges will be essential for transitioning from isolated pilots to enterprise-wide, GxP-compliant AI systems.

Model Drift and Performance Decay: AI models, especially those trained on historical process data, are susceptible to performance degradation as input distributions shift over time. It will be critical for the industry to embed continuous monitoring

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and drift-detection algorithms, such as Kolmogorov–Smirnov or population stability index (PSI) tests. Trigger-based retraining frameworks should be part of model life cycles.

Black-Box Models: Deep neural networks and ensemble models often lack interpretability, complicating regulatory validation and QA review. To mitigate that problem, organizations increasingly use interpretable surrogates such as shallow decision trees or rule-based systems for validation purposes, then using post hoc explainability tools to generate audit-ready justifications.

Data Fragmentation and Infrastructure Limitations: AI performance depends on integrated, high-quality datasets across the biomanufacturing value chain. This requires investment in unified data architecture, such as data lakes and real-time extract–transform–load (ETL) pipelines connecting laboratory information management systems (LIMS), enterprise resource-planning (ERP) systems, MES, and PATs. Interoperability and metadata governance are foundational to AI-readiness.

Siloed Functions and Governance Misalignment: AI initiatives frequently stall due to misalignment among IT, data science, QA, and manufacturing teams. A co-ownership model, by which cross-functional teams govern algorithm deployment, validation, and monitoring, will be essential to institutionalizing AI across GxP environments.

Strategic Enablers for Long-Term AI Maturity: Future-ready manufacturers are exploring next-generation tools such as

- digital twin orchestration platforms for dynamic, in silico simulation of process and quality outcomes
- generative design models that automate process optimization, protocol development, and scale-up pathways
- AI-assisted regulatory intelligence tools that support submission drafting, compliance scanning, and version-controlled documentation.

Together, such strategies enable a shift from experimental applications to scalable, auditable, and strategically governed AI ecosystems, positioning organizations to meet emerging global regulatory standards for digital and AI-driven biomanufacturing.

Foundations of Smart Manufacturing

AI is no longer just an emerging concept in biomanufacturing; it is becoming a foundational capability. Across upstream optimization, downstream control, quality analytics, and scientific knowledge synthesis, AI is redefining how biologics are developed, produced, and assured.

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This transformation represents more than a technological upgrade; it signals a fundamental shift in bioprocess logic, from reactive correction to predictive precision and adaptive learning. As illustrated by real-world cases such as Amgen's AI-driven yield optimization, well-validated AI systems can deliver significant gains in performance, efficiency, and compliance, within the rigorous demands of GxP-regulated environments.

However, realizing the technology's full potential will require more than models and infrastructure. It demands rigorous validation frameworks that satisfy regulators and QA auditors as well as seamless digital integration throughout production life cycles. In addition, a new generation of cross-functional professionals who are fluent in both bioprocess science and algorithmic reasoning are needed to interpret, validate, and scale AI responsibly.

The convergence of ML, digital twins, and automation is establishing the foundations for smart biomanufacturing, in which intelligent systems complement human judgment, drive innovation velocity, and ensure resilient, high-quality therapeutic manufacturing. The question facing the industry is no longer whether to adopt AI, but how to embed it ethically, strategically, and at scale.

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Smart Design

How Digital Tools Are Revolutionizing Cleanroom Engineering

John DeVitis

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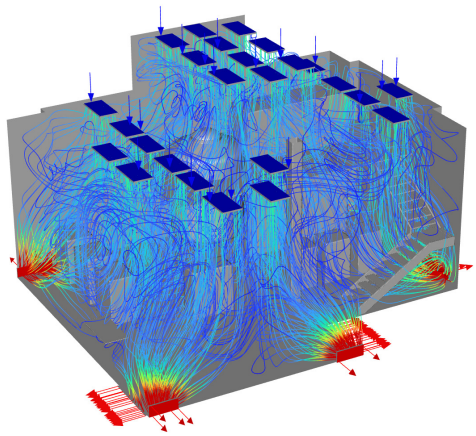
Pharmaceutical facilities are growing in complexity, and equipment needs must evolve to meet the fast-changing demands of drug innovation. Engineers face increasing difficulties keeping up, especially when ensuring optimal environmental conditions within critical cleanroom spaces on the drug production floor. Advanced digital tools are ushering in "smart design," revolutionizing how pharmaceutical facilities are engineered and validated. Integration of computational modeling — such as computational fluid dynamics (CFD) and building information modeling (BIM) — can transform cleanroom design and validation and shift operations from reactive problem-solving to proactive optimization.



Digital tools such as building information modeling (BIM) can enable proactive optimization of cleanroom design.

The Shift to Digital Cleanroom Design

The traditional approach to cleanroom engineering (based on previous experiences and trial and error) is struggling to keep pace with modern pharmaceutical demands. Needs for rapid implementation, modular scalability, and tight compliance make the design of clean spaces more complex than ever. Thus, digital tools such as CFD and BIM are essential. CFD can predict and analyze airflow behavior in a virtual environment, whereas BIM uses inputs on facility-component specifications to create a unified, data-rich digital representation of a site's geometry, systems, and construction sequencing. When complementing each other, such technologies can enable seamless coordination, early issue identification and cleanroom compliance and performance before construction begins. With the pharmaceutical sector embracing rapid, flexible facility development, digital tools are more important than ever.

The Power of Predictive Analysis: CFD in Action

CFD is an invaluable tool for modern cleanroom design, enabling engineers to quantify and visualize complex airflow patterns virtually. Such predictive capabilities are ideal for optimizing performance of specialized equipment or for mitigating against the complexities of designing nontraditional layouts. Airflow

verification is part of facility certification. If airflow issues are identified during assessments at the stage when components already are installed, then significant rework may be needed to rectify problems, causing costly delays and escalating expenses.

When used early in the design process, CFD can create a detailed simulation that enables engineers to test potential scenarios and refine layouts before physical construction, minimizing the risk of issues appearing during certification. Such simulations create comprehensive models of cleanroom environments, capturing details such as room and equipment boundaries, airflow inlets and outlets, and various environmental conditions. Then a room is segmented into three-dimensional (3D) cells, and fluid-dynamic equations are applied to predict airflow velocities, pressure gradients, and the movement of particles. Results illustrate air movement and potential risks, allowing quantifiable results to be extracted. Such a proactive solution is vital for large and/or irregular equipment layouts and for modeling unconventional solutions, such as relocating a high-efficiency particulate air (HEPA) filter or adjusting ceiling heights.

Laying a Digital Foundation with BIM Technologies

BIM is an ideal complement to CFD, grounding the latter's insights in physical reality. Beyond being a 3D drafting tool, BIM can act as a shared digital ecosystem for a facility project's entire life cycle, including design, construction, and operations. When building modular cleanrooms, BIM platforms are vital for orchestrating every stakeholder, such as designers, contractors, vendors, and compliance teams, to ensure that issues are identified and resolved proactively.

BIM technologies allow the coordination of cleanroom layouts with electrical, plumbing, and fire-protection networks as well as heating, ventilation, and air conditioning (HVAC) systems. That significantly reduces installation errors and rework by visualizing system interactions, ensuring smooth sequencing and optimized spatial efficiency. BIM models also function as living models during commissioning and design of future renovations. In regulated environments, referencing a validated BIM model streamlines audits and inspections, enhancing traceability and supporting proactive quality management.

Together, BIM technologies and CFD offer a multidimensional view of how form and function intersect. Engineers can test how structural changes influence air flow, while designers tweak layouts for performance without waiting for certification to reveal

Integration of CFD and BIM technologies has reshaped cleanroom design fundamentally, moving it toward **PROACTIVE OPTIMIZATION.**

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problems. Such real-time, crossdisciplinary collaboration enhances accuracy, accelerates consensus, and drives informed decisions.

Harnessing Smart-Design Benefits

A recent cleanroom project that AES Clean Technology supported provides a compelling example of the power of smart-design solutions. The goal was to develop an International Organization for Standardization (ISO) class 8 cleanroom designed for substantial bioprocessing equipment. The original layout specified HEPA filters on an elevated ceiling section to facilitate bioreactor-lid removal. However, space limitations above the ceiling required repositioning those filters to the raised section's vertical walls — a critical alteration that needed thorough performance assessment.

Such architectural modifications are common, but their effects on air flow are often unpredictable. To evaluate the revised design, three vital parameters were established: nominal air-change effectiveness, minimum local air-change effectiveness, and air-change effectiveness volume ratio. Those metrics formed a strong basis for comparing various design iterations, providing quantifiable data to inform choices and guarantee environmental compliance. That is especially vital in cases requiring consistent air distribution.

The CFD analysis confirmed that moving HEPA filters to the vertical walls would not diminish room performance; in fact, some metrics showed minor gains. Critically, the simulation also uncovered optimization opportunities, specifically addressing potential air stagnation beneath elevated equipment platforms, a risk that otherwise might have remained hidden until after construction.

The optimization process yielded key strategic insights. Optimizing HEPA-filter placement significantly boosted air distribution. Integrating additional low-wall returns in key areas improved localized ventilation. And monitoring air velocities under elevated platforms enhanced circulation. Those results highlight the intrinsic value of simulation-driven design: not just for validation, but for active performance enhancement. By detecting subtle inefficiencies early, the project team made data-backed decisions that improved the room's performance and reduced future risks. Such virtual-evaluation capability empowers engineers to validate changes, proactively resolve issues, refine air distribution, and substantiate design choices with solid data.

A Smart Future for Cleanroom Design

Integration of CFD and BIM technologies has reshaped cleanroom design fundamentally, moving it toward proactive optimization.

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Digital instruments are now indispensable for managing complex projects and meeting stringent regulatory demands efficiently. As digital design matures, artificial intelligence (AI) and machine learning (ML) are likely to enhance facility planning further, from autogenerating optimal layouts to refining airflow strategies. Such technologies signal an era of intelligent, adaptive cleanroom design.

The aim is to create efficient, compliant, and flexible cleanrooms. Simulation and digital collaboration are key to achieving this because they mitigate risk and enhance results, equipping facilities for modern pharmaceutical manufacturing. The clear return on investment lies in reduced delays, streamlined processes, and improved patient outcomes due to consistently controlled environments.

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Global eQMS Modernization for Biopharmaceutical Developers

Strategic Pathways to Digital Transformation

Stuart Angell, Phil Brown, and Mike King

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Small- to medium-sized enterprises (SMEs) in the biopharmaceutical industry face distinct challenges when modernizing their quality management systems (QMS). They must balance limited resources against regulatory demands. As innovators driving therapeutic breakthroughs, such organizations must approach implementation of electronic QMS (eQMS) with strategic precision to ensure sustainable compliance and operational excellence.

Beyond Document Digitization

The journey toward effective eQMS implementation transcends simple document conversion. Although many biopharmaceutical SMEs leverage Microsoft SharePoint or Google Drive systems for document management, digital transformation requires deeper integration with business processes. The distinction between digitizing documents and leveraging data for strategic decision-making represents a critical differentiator for organizations seeking competitive advantage. Successful implementation begins with understanding the fundamental purpose of a QMS within a biopharmaceutical context before determining which processes merit digital enhancement. An efficiently structured QMS typically requires only core procedures covering organizational structure, personnel training, and postmarket surveillance.

However, biopharmaceutical organizations can accumulate excessive documentation over time, sometimes expanding to hundreds of procedures that impede rather than enhance operational efficiency. Focusing on critical processes while avoiding unnecessary complexity proves to be essential for sustainable implementation.

Resource Considerations

Commercial viability remains paramount for biopharmaceutical SMEs balancing multiple strategic objectives (e.g., immediate profitability, acquisition attractiveness, and investment

opportunities). Such organizations frequently operate with constrained quality assurance and regulatory affairs (QARA) expertise, with professionals managing diverse responsibilities across functions. This challenge becomes particularly acute when therapeutic products originate from academic or research environments with few regulatory-compliance considerations.

Implementation hurdles extend beyond resource limitations; they also include data-management challenges specific to biopharmaceutical development. Organizations must address scattered clinical data and integrate new systems with existing laboratory processes. Such a transition requires careful orchestration, particularly for organizations with limited technical infrastructure supporting complex biological-product development.

Success stems from conceiving of digitization as an **EVOLUTIONARY** journey that supports continuous **IMPROVEMENT** in biomanufacturing.

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Global Regulatory Navigation for Biologics

The biopharmaceutical regulatory landscape introduces additional complexity when implementing global eQMS solutions. Although core QMS requirements remain relatively consistent worldwide, regional implementation details and auditing practices for biological products can vary significantly across markets. Biopharmaceutical organizations therefore must navigate intricate data-handling requirements that differ among markets, particularly for patient-derived biological materials and clinical-data management. Such variations influence critical decisions regarding manufacturing locations for biological products and necessitate expanded quality-system scope, encompassing third-party service partners throughout the supply chain.

Maintaining consistent quality standards while adapting to local regulatory nuances becomes especially challenging when SMEs begin offering their products globally. Organizations must design eQMS architectures that accommodate different regulatory frameworks while maintaining efficiency across biologics development, manufacturing, and distribution operations.

AI Integration for Quality Processes

For biopharmaceutical enterprises, whether to adopt artificial intelligence (AI) depends on alignment with specific therapeutic-development needs and operational maturity. Early opportunities emerge in regulatory intelligence-gathering, in which AI can accelerate understanding of requirements for biological products across markets. For combination products and companion diagnostics, AI can assist in navigating classification differences between regulatory frameworks.

AI integration could prove to be particularly valuable for risk management in biological-product development by connecting

different QMS processes and identifying emerging safety signals across development phases. The technology can enhance state-of-the-art assessment and clinical-performance evaluation by analyzing therapeutic market trends and feeding insights back into formulation and process development. For example, companies can use AI to look at multiple data sources (e.g., social media, company inboxes, and audio files from customer services) and extract additional information regarding their products that may not be found through standard complaint-reporting processes alone. R&D, quality, and regulatory teams can implement such product-performance data to drive remediation of current products in the market and update products based on the feedback acquired. However, biopharmaceutical organizations must ensure that robust data management underpins any AI implementation because data integrity directly affects product commercialization and efficacy.

Cultivating Quality Culture in Biopharmaceutical Innovation

Creating effective eQMSs transcends technology implementation; it requires cultivating an organizational culture in which quality serves as a catalyst for therapeutic innovation rather than a regulatory obligation. When executives champion that perspective, quality management transforms into an integral component of biopharmaceutical success.

Industry associations can support that transformation, particularly for biopharmaceutical SMEs. Such associations can help to ensure that auditors understand digital processes while translating abstract concepts into tangible benefits for therapeutic developers. Those efforts can amplify small organizations' voices, safeguarding the innovation pipeline that frequently begins with SMEs before advancing to large biopharmaceutical companies.

Strategic Implementation Framework

Biopharmaceutical organizations should begin by reviewing existing processes against therapeutic-development needs and eliminating redundant procedures. That evaluation should identify critical gaps in areas such as design control and validation. Following assessment, organizations can prioritize key processes for digitization rather than attempting a complete system overhaul. Implementation should begin with foundational systems supporting product-development documentation and training records. Each digital implementation must align with an organization's risk-management approach while considering organizational culture and strategic objectives. Such a measured approach allows digital transformation to proceed naturally

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without overwhelming staff with simultaneous changes across multiple development processes.

The Future of Quality Management

The integration of eQMS among biopharmaceutical SMEs requires strategic foresight that balances innovation and compliance. Although emerging technologies offer compelling opportunities, implementation must address true organizational needs throughout a therapeutic-development life cycle.

Success stems from conceiving of digitization as an evolutionary journey that supports continuous improvement in biomanufacturing. That perspective can enable organizations to develop adaptive systems that respond to shifting regulatory requirements while maintaining operational efficiency. The key lies in strategically leveraging technology to enhance core quality processes, building robust systems that drive both compliance and sustainable growth in the international biopharmaceutical market.

Biopharmaceutical organizations that excel will maintain simplicity and utility as guiding principles, ensuring that technological implementation enhances rather than complicates therapeutic development. A measured approach enables biopharmaceutical SMEs to establish QMSs that not only satisfy regulatory requirements, but also catalyze operational excellence throughout a therapeutic-development life cycle.

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How Can AI Speed Life-Saving Cures to Patients?

Chirantan Chatterjee and Tinglong Dai

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For patients facing cancer, heart disease, diabetes, or Alzheimer's, the wait for new therapies can feel endless. A promising discovery in a laboratory today could take a decade or longer to become an approved treatment. Tragically, many people who could benefit from tomorrow's cures do not have the time to wait. Such bottlenecks are familiar: Researchers painstakingly test and try — running experiment after experiment, discarding countless dead leads before a viable pathway emerges. Data collection and analysis demand extraordinary attention to detail. Even once a breakthrough occurs, peer review and regulatory processes add years. That methodical system safeguards patients but slows progress.

Imagine if the entire process could be compressed. Possibilities and hypotheses could be tested against each other in seconds instead of months. Data analysis could be accelerated by orders of magnitude. And researchers could spend less time buried in paperwork and more time pursuing new ideas. That is the goal of an emerging array of artificial intelligence (AI) tools.

AI in Action

Major biopharmaceutical organizations and companies are investing accordingly into AI technology. Insilico Medicine has advanced an AI-designed small molecule into phase 2 trials for idiopathic pulmonary fibrosis (**1**). Sanofi's US$5.2 billion collaboration with Exscientia continues to hit milestones, and a three-way effort with Sanofi, OpenAI, and Formation Bio is producing concrete tools for drug development (**2, 3**). Meanwhile, the AI–infrastructure layer is maturing: Recursion's NVIDIA-powered stack and Generate:Biomedicines' first-in-human AI-generated proteins compute meaningful biological insights (**4**). On the clinical-operations side, Sanofi, Formation Bio, and OpenAI have begun rolling out their Muse model to accelerate subject recruitment and streamline late-stage trial execution, including phase 3 multiple-sclerosis studies (**5**). The implications are profound. By compressing discovery cycles and lowering attrition, AI could shorten patent lives as competition arrives earlier than ever before, creating an access dividend for patients.

AI also can reopen neglected frontiers. In the antibiotics sector, AI-guided discovery recently surfaced abaucin, a narrow-spectrum compound active against *Acinetobacter baumannii* — a World Health Organization (WHO) priority pathogen — reviving a field long considered to be uneconomical (**6**). And in protein therapeutics, generative models are informing first-in-human studies and facilitating billion-dollar partnerships, suggesting that design space — not just screening throughput — is changing (**7**).

But acceleration alone will not save lives. AI can generate promising leads faster than trial systems can validate them, risking an evidence backlog. Regulators are drawing the outlines of a remedy. The US Food and Drug Administration's (FDA's) 2025 draft guidance explains how AI-generated information can support decisions about the safety, efficacy, and quality of drugs and biologics (**8**). Similarly, the FDA's 2023 discussion paper on AI in drug manufacturing anticipated concerns for model validation, data provenance, and cloud oversight (**9**). Those materials mark the beginning of an AI-ready playbook, including expectations for model life-cycle management (e.g., documentation of training data, drift monitoring, and change control when algorithms and inputs evolve).

Biomanufacturing is becoming AI-native as well (**10**). Cell-line development (CLD) is shifting from incremental design of experiments (DoE) to model-informed design. Process analytical technology (PAT) combined with machine learning (ML) is moving monitoring toward prediction, and "digital twins" of upstream and downstream steps are starting to support real-time decision-making and accelerated deviation root-cause analysis (**11**). Real progress will be measured on factory floors: AI that can shorten technology transfer, flag scale-up risks before they can reduce yields, and accelerate batch-record deviation triage already is emerging in practice. Such capabilities augment rather than replace quality systems.

Access to computing capability will matter as AI technologies become prevalent. Computing power is a new kind of scientific capital, but it should not be a gating factor. Philanthropic investments are helping: the Chan Zuckerberg Initiative (CZI) is building one of the world's most powerful nonprofit graphics processing unit (GPU) clusters for life-science research, a step toward democratizing discovery tools (**12**). And the field is embracing open challenges: the 2025 Alzheimer's Insights AI Prize invited teams to build agentic AI that coule turn existing data into new hypotheses — another way to accelerate breakthroughs without reinventing data collection from scratch (**13**).

The biopharmaceutical sector can transform from a business of serendipitous breakthroughs into one of systematic, global, and equitable **INNOVATION.**

The future of AI in biopharmaceuticals will not be about machines replacing humans. It will be about "centaurs" — teams through which humans and AI work together, each amplifying the other's strengths. Companies can treat every experiment as data for the next iteration. Regulators can codify standards for AI-native facilities and AI-assisted manufacturing. Funders can keep investing in shared computing power and open datasets. Clinicians can demand transparent tools that they can trust and explain.

AI already has delivered antibiotic candidates and first-in-human proteins — goals that were once thought to be unreachable. But the true promise lies in more than rapid discovery; it includes translating that speed into evidence, regulation, and adoption. The biopharmaceutical sector can transform from a business of serendipitous breakthroughs into one of systematic, global, and equitable innovation. For patients, that could mean something more important than price and profit: time.

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