



IFPMA



Innovation in Pharmaceutical Manufacturing

Artificial Intelligence

Artificial intelligence in pharmaceutical manufacturing – navigating innovation and regulation

Artificial Intelligence (AI) and Machine Learning (ML) are rapidly transforming various sectors, and the pharmaceutical manufacturing industry is no exception. This paper explores how the pharmaceutical industry may use individual applications of AI in pharmaceutical manufacturing and control.

It describes the evolving regulatory landscape and provides key considerations for national regulatory authorities (NRA) when reviewing regulatory submissions or inspecting manufacturing sites that use or describe AI technologies in their processes.

What is the potential of AI in pharmaceutical manufacturing

The adoption of AI in pharmaceutical manufacturing and control enhances efficiency, accuracy, and confidence in future manufacturing and quality outcomes by automating repetitive tasks and analyzing large datasets using statistical models. Key potential benefits include:

Increased agility and efficiency

AI can be used to enhance speed of decision-making on the manufacturing floor, improve operations, and boost efficiency by augmenting the human workforce. This can lead to more robust processes and shorter cycle times.



Enhanced accuracy and innovation

AI can be leveraged to execute repetitive tasks with greater accuracy, positively influencing "right first time" efforts and data integrity. Furthermore, it possesses the capability to be used to perform real-time analyses of data at large scale and resulting predictions or decision making.



Improved quality assurance performance

AI can be implemented to facilitate the transformation, analysis, and interpretation of data throughout the drug product manufacturing lifecycle, ultimately leading to better patient and customer outcomes.



Real-world applications of AI and ML in manufacturing

AI and ML can be applied across various processes and by different functions within pharmaceutical development and manufacturing, demonstrating tangible benefits. Examples of potential applications include, but are not limited to:



ML models for process prediction or control (digital twins of manufacturing processes)

ML models are employed to predict reality with proposed outcomes (for example, predicting the yield of a monoclonal antibody manufacturing process). These methodologies involve creating so-called "digital twins," which are digital models of an entire manufacturing process or of an individual step in a process. The "digital twin" translates historical experience or designated process development data with the same or similar product or their manufacturing process into actionable information. Digital twins can be used either as part of the control system or outside the established control system (for improving planning and scheduling of production runs), with a different resulting level of risk.



Deep learning for automated visual inspection (AVI)

Deep learning algorithms have been utilized to support the quality assurance process to comply with prior-established parenteral product specifications/requirements. As an example, while 100% in-process visual inspection of all filled parenteral products is a regulatory requirement in some jurisdictions, the manual inspection by staff can create a bottleneck. Further, the use of conventional algorithms to support automated visual inspection often produces a significant number of false positives. Deep learning-powered algorithms and computer vision can help reduce false reject rates, minimize manual re-inspection, prevent delayed product release, and reduce the loss of product that comply with the required specifications.



Generative AI (GenAI) for text management

Beyond direct manufacturing operations, GenAI applications can help generate content proposals for regulatory required reports and summaries that could be used in regulatory dossiers, trend analysis, improving readability and accuracy in quality reporting, and enhancing knowledge management through advanced search and report generation in technical development. For this type of application, GenAI technologies will support the work of trained individuals (i.e. "Human in the Loop - HITL") and improve readability and accuracy in quality reporting while reducing the effort needed¹.

The evolving regulatory landscape

Many NRAs around the world are developing regulations and guidance on application of AI and are generally taking a risk-based approach to oversight of AI used in drug development and manufacturing. A key consideration is determining the level of detail that should be available for routine inspections versus what needs to be submitted in the regulatory dossier, an issue that is especially important for marketed products and management of post-approval changes.

Many NRAs including both the FDA (U.S. Food and Drug Administration) and the EMA (European Medicines Agency) show a strong and comparable level of regulating principles of the application of AI across the medical life cycle. Today, most NRAs published reflection papers and draft guidance for further discussions in this area.



Examples of activities and publications by selected jurisdictions

US FDA: Within the drug space, the FDA established the CDER Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) Initiative, identifying AI/ML in manufacturing as a priority. A number of guidance documents have been published:

- "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products" (draft guidance FDA-2024-D-4689, 2025²), which has a broad scope across the drug product lifecycle, including manufacturing and provides guidance on how AI applications could be tested and documented.
- "Artificial Intelligence in Drug Manufacturing"³ (CDER discussion paper, 2023) sharing opportunities where the agency sees AI applications to be helpful.
- The agency also engages in efforts like the "Digital Health & Artificial Intelligence Glossary"⁴ (2024) and issued thoughts in draft guidance on AI-enabled device software functions.
- In addition, a large number of additional guidance has been issued for the device/diagnostics space by CDRH.

EU: The European Union adopted the EU AI Act, a horizontal regulation that establishes legally binding requirements for AI systems based on their assessed risk level. This regulation is not specific to the pharmaceutical industry, but across sectors, and requires additional interpretation for its applicability to pharma.

The EU and FDA also recently jointly published a paper on "Guiding Principles of Good AI Practice in Drug Development"⁸ (2026), although it is not specifically addressing use of AI in manufacturing.

WHO: Is in the process of developing a "Points to consider" guidance for inspectors on advanced manufacturing topics, including AI.

ICH: QIG "Points to consider" - Chapter 5⁹, which provides a risk framework on criticality of different models in pharmaceutical development and manufacturing. This document predates widespread AI or ML models in use, but the principles for models are still technically relevant.

Additional examples focused on the pharmaceutical sector:

EMA "Reflection Paper on the Use of AI in the Medicinal Product Lifecycle"⁵ (EMA/CHMP/CVMP/83833/2023 - final version released in September 2024)

demonstrating the opportunities for AI applications. This paper is not specific to manufacturing uses of AI in the pharmaceutical industry but gives an overview across the medicinal product life cycle.

EMA Quality Innovation Group (QIG):

Within EMA, the cross-functional QIG with regulatory reviewers and inspectors leads the efforts on AI applications use in manufacturing and aspects of registration relevance and reporting in dossiers and documents available for review in inspections. The QIG hosted a workshop (Listen and Learn Focus Group) on "Digital applications for Manufacturing" in 2023 and released the draft document "Preliminary Considerations on Process Models"⁶ (March 2024) with applicability for AI-driven models, if implemented.

EMA/European Commission:

AI in manufacturing (draft Annex 22 of the EU GMP Guidelines)⁷ addresses AI and ML aspects related to GMP expectations when using AI in applications. This draft guideline links to the "Computerized System" guidance (EU GMP Guidelines, Annex 11) and has its basis in the 'Documentation' guidance (EU GMP Guidelines, Chapter 4) which currently covers static, deterministic machine learning models in GMP but explicitly excludes dynamic, probabilistic, and generative AI, including large language models (LLMs). See considerations on Annex 22 in the following section.

Regulatory considerations and key enablers for the use of AI in pharmaceutical manufacturing

Overall, AI is a rapidly evolving space with also potentially many diverse applications in the GMP and manufacturing area. This calls for a regulatory enabling environment focused on science and risk-based regulatory approach and most importantly, flexibility.

Until recently, no specific regulation that directly regulates AI implementation in pharma manufacturing had been published. The recently crafted draft EUGMP regulation, Annex 22 is the first document to introduce specific exclusions, such as the use of GenAI or dynamic models for high-risk GMP applications but is worded very prescriptively and restrictively. As the EU annexes represent regulation, not just guidance, and potentially may be adopted internationally in the future through PIC/S (Pharmaceutical Inspection Cooperation Scheme), it will be important to see improvements in the initial final version.

Still, on a higher level of discussion, several areas of regulatory challenges are currently being debated and represent opportunities for advancing safe and effective use of AI in pharmaceutical manufacturing:

Creating a sector-specific (pharmaceutical) AI risk framework

A comprehensive, harmonized risk management framework for AI models in the pharmaceutical manufacturing sector is needed, as technical standards can then be derived from such a framework. For applications in manufacturing/GMP, the foundational element can be the ICH Q9 framework.

Promoting global harmonization

As AI use in manufacturing increases, there is a unique opportunity to establish a globally aligned regulatory baseline. If jurisdictions diverge early, this will create regulatory uncertainties, inconsistent expectations, and ultimately no benefit to patients receiving the same products worldwide.

Initial signs of a strong alignment in the current regulatory discussions (e.g., in US or EU) are positive; however, risk of divergence remains. For example, early drafts of the EMA QIG "Preliminary considerations for process models" referenced the ASME V&V 40 methodology, also used by the FDA. Nonetheless, this terminology is no longer used in the EMA QIG "vi", illustrating how alignment can diverge over time. As with other aspects of medicines regulation, regulatory authority guidelines (rather than standards) should be developed. These facilitate convergence amongst regulatory bodies. A very recent positive example is also the joint EMA/FDA document on "Guiding Principles of Good AI Practice in Drug Development", although the document does not reference the use of AI for manufacturing/GMP specifically.

Allowing for an evolution of oversight focus

The onset of large-scale use of AI also for models used for developing or controlling manufacturing processes requires an evolution of previously stated terminology and underlying expectations. For example, the methodology for assessing process models - including those using AI or ML - is shifting from "impact" to product quality (ICH Q8-10 Points to Consider document) to a broader concept of "context of use," then "model risk" or "model use risk," which incorporates "model influence" and "decision consequence" (ASME V&V 40, FDA CDER AI guidance, EMA QIG Preliminary Considerations on process models draft March 2024).

Addressing unique AI-specific hazards highlighted by NRAs

Automation bias and erosion of human oversight: Although the process today is to include a human in the loop to supervise AI systems, there is an inherent risk that human oversight will erode. This “automation bias” (i.e. the willingness of the human user to accept the automation/AI results without thorough check) is not entirely new, but possibly more prevalent given the human-like outputs of some GenAI/LLM models. Provisions to ensure that the HITL is trained/qualified and that the responsibility is well embedded in the role are important.

Data quality and bias: Limitations in the quality, origin (e.g. synthetic data), size, and representativeness of datasets for training AI models may introduce bias and raise questions about the reliability of AI-driven results. Algorithmic bias can lead to incorrect results and decisions due to training data limitations, or erroneous assumptions. These challenges are not entirely AI specific, so some of the established best practices of statistical (trained) modeling, such as good data labeling principles, and the separation of training from test data sets, could serve the purpose for ML models as well without additional AI specific new rules.

Explainability and interpretability: The complex computational and statistical methodology underpinning AI models can create uncertainties in understanding how they arrive at conclusions, necessitating methodological transparency. The concept of “explainability,” originally used in the context of AI systems making decisions based on personal data, refers to understanding why an AI system made a decision. In many pharmaceutical applications, the focus can be on “interpretability” i.e., the meaning of its output in a context. Given the use of AI in manufacturing in a regulated environment – with established framework of making quality decisions based on other complex control systems – “interpretability” might be sufficient.

Lifecycle maintenance and data drift: Models' performance can change over time or across deployment environments when new data inputs differ from training data (i.e., data drift). This challenge is addressed by ongoing lifecycle maintenance and establishment of proper data models and ontologies. This is similar to other training-based models, and indications of expectations can be found for example in process analytical technology guidelines by EMA and FDA.

Autonomous learning: Autonomous learning/ updating of algorithms can be seen as a challenge in the conventional GMP framework, which typically assumes “locked” algorithms that are validated/tested. While most current manufacturing applications use “locked algorithms,” autonomous learning is a potential future strength of AI, and regulatory tools like Post-Approval Change Management Plans (PACMPs) describing predefined performance criteria for the updated algorithms may emerge to address it.

Changing mindset and tackling perceived hurdles

Promoting regulatory understanding and acceptance: Lawmakers, as well as NRA reviewers, and inspectors could evaluate the credibility of AI outputs for manufacturing contexts of use, and risk control measures to ensure a well-informed regulatory perspective.

Getting to a solid common understanding of technical complexity: AI is a highly technical subject, requiring deep understanding to evaluate risk and intended use, which can lead to potential misunderstandings during inspections due to time constraints. The common understanding can be built through comprehensive training of inspectors for the new technology, supported by industry expertise.

Creating common expectations for AI/digital solutions: NRAs and stakeholders may apply different and somehow higher standards to digital solutions compared to human solutions because they are less familiar with the new technology. The “human-like” performance of some AI systems (i.e. GenAI or LLM) also brings up the challenge of having to measure the performance of the human so the performance expectations for the AI system can be set appropriately (i.e. same standard).

Focusing on modeling expertise: Regulatory discussions are partially driven by formalized computer system validation (CSV) considerations (e.g., drafted EU- GMP Guidelines, Annex 22 as an extension of Annex 11). Discussions could benefit from incorporating the actual expertise with the model development and validation process, and regarding AI application and regulatory guidance from a point of use perspective. This is to weigh the benefit of the additional knowledge gained vs. not solely through a formalistic "AI rule" perspective.

Raising awareness of regulatory policy discussions on AI applications in manufacturing/ GMP: There should be a clear distinction between "AI in manufacturing" and AI applications in other parts of the pharmaceutical lifecycle, especially in clinical development space with the use of human trial data. Different policies as described in existing regulations (i.e. established GMP frameworks for example CFR part 11, Eudralex Chapter 4 etc.) could be applied, recognizing that data from manufacturing operations is largely not personal, or medical, nor ethically challenging to process or store. While the use of AI for handling patient or medical data is inherently more complex and carries a higher risk (like privacy, ownership, ethics, and bias to certain parts of the patient population), the manufacturing/CMC data space is generally covered by existing technical and GMP compliance-related policies, including but not limited to GMP expectations around data, such as data integrity.

Leveraging existing guidance to enable the use of AI

For AI applications as a relatively novel technology in manufacturing, the question arises whether completely new guidance is needed to control additional risk.

One aspect that is critically needed, especially in an emerging field, is a harmonized glossary of terminology. Certain terminology like "risk," "ethical AI," or "explainability" have far-reaching definitions and applicability for use of AI in GMP/manufacturing, which might unnecessarily create a wrong perception of risks and hazards. Several glossaries have already been developed (including the "FDA Digital Health and Artificial Intelligence Glossary", but an international harmonization, either as seen in the recent publication of AI principles by FDA and EMA in January 2026, or even through ICH would be very helpful.

The pharmaceutical industry sees value in first leveraging existing policies and regulations for AI as a starting point. For AI-specific hazards that remain unaddressed, NRAs can develop additional targeted requirements. We can address current guidance gaps through an agile approach that allows future adjustments. For example, regulators can adapt existing frameworks such as 21 CFR Part 11 (US FDA), Annex 11 (EMA), and ICH Q8–10.

Conclusion

The use of AI and ML presents promising new tools to be adopted in the regulated pharmaceutical manufacturing space.

Because manufacturing data is generally less personal or ethically sensitive than data in other areas of the pharmaceutical business and, given the robust regulatory framework already in place through GMP requirements, pharmaceutical manufacturing can be considered a controlled environment for deploying AI and ML tools, provided appropriate guardrails and rigorous quality risk management are applied. Or, in brief terms, as a "safe space to deploy the AI and ML tool set".

While many existing regulations and guidance require only interpretation or scope extension to encompass AI, a few unique characteristics of AI demand proactive risk-control measures and transparent identification of residual risks to fully harness the technology's benefits. In principle, the field of AI in pharmaceutical manufacturing, which is emerging and has few existing guidance, offers a unique opportunity for early alignment, as opposed to addressing diverging rules later.

Global convergence, alignment, and harmonization of focused, risk-based AI regulatory guidance is essential to drive widespread, consistent adoption in pharmaceutical manufacturing, reduce compliance uncertainty, and enable proportionate, effective safeguards.

Endnotes

1. [Applying Machine Learning to the Visual Inspection of Filled Injectable Drug Products](#), Technology/Application note in PDA Journal of Pharmaceutical Science and Technology, 2023
2. [Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products](#), USFDA, 2025
3. [Artificial Intelligence in Manufacturing – Discussion Paper](#), USFDA, 2023
4. [FDA Digital Health and Artificial Intelligence Glossary – Educational Resource](#), USFDA, 2024
5. [Reflection Paper on the use of Artificial Intelligence in the medicinal product life cycle](#), EMA, 2024
6. [Preliminary QIG Considerations regarding pharmaceutical process models](#), EMA, 2024
7. [EudraLex - Volume 4 - Good Manufacturing Practice \(GMP\) guidelines, Draft Annex 22: Artificial Intelligence](#), European Commission, 2025
8. [Guiding Principles of Good AI Practice in Drug Development](#), USFDA, 2026
9. [ICH Quality Implementation Working Group. Points to Consider: Implementation of ICH Guidelines – Chapter 5](#), ICH, 201

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