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Short communication

AI potential in the pharmaceutical industry

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Introduction

Digitalization of any manufacturing industry is a key step in any progress of the production process (Hole et al., 2021). The pharmaceutical industry is continuously seeking opportunities to embrace the advances in new technology and computerized systems in GMP manufacturing processes. The integration of AI across pharmaceutical operations is transforming traditional practices, from drug discovery to patient care, enabling more efficient research, development, and manufacturing processes (EFPIA, 2024).

Materials and methods

As a targeted narrative review, this paper focuses on existing research regarding recent technological applications, regulatory drafts, and industry practices to evaluate the impact, utility, and risk profile of AI tools in GMP environments.

Results and discussion

What is AI?

Artificial intelligence (AI) combines various smart behaviors and processes that are created by computer models, algorithms, or a set of rules. They allow machines to mimic human thinking skills such as learning and problem-solving, and this behavior is called AI. Machine learning (ML) is a part of AI and it works by using data-trained algorithms. Deep learning (DL) is a subset of ML that is somewhat based on how the human brain is structured. In the pharmaceutical manufacturing context, AI, ML, and DL are increasingly pivotal in pharmaceutical data analytics, automation (Debnath et al., 2025) and performing tasks enabled by rule-based decisions with human oversight with potential for eventual minimal intervention (EFPIA, 2024).

AI in the pharmaceutical industry

AI is a rapidly evolving space with potentially many diverse applications in the GMP and manufacturing area (IFPMA, 2026), also AI is revolutionizing individualized therapy, research, and drug development. In the pharmaceutical industry, it can be used to simplify medicine production procedures, enhancing quality control, and streamlining supply chain management that saves valuable time and money (Debnath et al., 2025). When developed and used correctly, AI/ML tools and methodologies can effectively support the acquisition, transformation, analysis, and interpretation of data within the medicinal product lifecycle, from early drug discovery to post-market monitoring (EMA, 2024).

AI in pharmaceutical manufacturing

Advancements in pharmaceutical manufacturing are increasingly driven by intelligent systems designed to replicate human expertise in response to rising process complexity and demands for efficiency and quality. Many of the pharmaceutical processes we use today are capable of being

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automated. In solid dosage forms, such as tablets, AI can help developers optimize formulations by evaluating critical parameters during formulation development. AI can also help predict and evaluate the physicochemical stability of oral formulations by reviewing vast data sets of drug properties, formulation variables, and environmental factors. When it comes to biological products, AI can help design proteins, peptides and nucleic acid therapeutics with improved properties, leveraging databases on protein structures and functions, to design models for optimizing therapeutic safety, efficacy, and immunogenicity (Debnath et al., 2025).

AI can enhance process monitoring and fault detection by using sophisticated algorithms to analyze real-time data from manufacturing equipment. This allows for the early identification of potential issues, thereby reducing downtime and maintaining production efficiency. Through advanced image recognition and data analysis, AI can improve quality control in manufacturing, detecting and pre-empting deviations in real-time, and ensuring products meet stringent regulatory standards. Furthermore, while AI can enhance quality assurance by supporting deviation trending and root-cause hypothesis generation, qualified personnel retain sole responsibility for final root-cause determination and CAPA approval. (EFPIA, 2024).

Regulatory considerations

The rapidly evolving field of AI/ML shows great promise for enhancing all phases of the medicinal product lifecycle (EMA, 2024). A risk-based framework must evaluate the operational context of AI in manufacturing, the degree of autonomy granted to the system, and the level of human oversight integrated into GMP decision-making (EFPIA, 2024). Some potential hazard from using AI may include: automation bias, data quality limitations, explainability and interpretability, lifecycle maintenance and data drift, and autonomous learning problems. This calls for a regulatory enabling environment. The draft EU GMP, Annex 22 is the first regulatory document to introduce specific exclusions, such as the use of GenAI or dynamic models in critical GMP applications with direct impact on patient safety, product quality or data integrity. However, its current wording remains highly prescriptive and restrictive (IFPMA, 2026).

Conclusion

AI as a principle is a new and digital way to run established processes more efficiently. AI has an immense potential to enable and augment the way APIs and medicinal products are developed, manufactured and commercialized. Industry must ensure it continues to act responsibly, and that its use of AI/ML remains trustworthy and compliant with current and evolving regulatory expectations to maintain its license to operate.

Ultimately, the integration of AI into pharmaceutical manufacturing represents more than a technological shift, it prepares us for the new Pharma 5.0 concept which adds human-centric design, sustainability, and ethical intelligent systems into the core framework of future pharmaceutical operations.

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