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Short communication

Artificial Intelligence in pharmaceutical quality assurance: opportunities and challenges

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Introduction

The pharmaceutical industry operates in a highly regulated environment where product quality, patient safety, data integrity, and compliance with Good Manufacturing Practice (GMP) are essential. Quality Assurance (QA) departments are responsible for maintaining robust quality systems, ensuring compliance with regulatory requirements, and supporting continuous improvement activities throughout the product lifecycle. However, increasing process complexity, large volumes of manufacturing and laboratory data, and the need for rapid decision-making have created challenges for traditional quality management approaches. Artificial Intelligence (AI) has emerged as a promising technological solution capable of improving operational efficiency, risk management, and supporting data-driven decision-making in pharmaceutical systems (EMA, 2024). AI technologies, including machine learning, predictive analytics, and intelligent automation, can support various QA activities such as deviation management, change control, corrective and preventive actions (CAPA), audit preparation, trend analysis, and documentation review (Nakka et al., 2026). AI can support document review, identification of errors, inconsistencies, and compliance gaps within GMP documentation systems.

The aim of this short review is to provide an overview of the potential applications of AI in pharmaceutical QA, as well as the associated challenges and regulatory considerations.

Applications of AI in pharmaceutical quality assurance

AI-based systems can analyze large datasets from manufacturing equipment, environmental monitoring systems, laboratory instruments, and quality management systems to identify hidden trends and detect anomalies in real time (Bhosale et al.). Predictive analytics can support proactive quality management by identifying potential deviations before they occur, reducing the risk of batch failures and improving process reliability.

Significant application of AI in QA is document management and review. Pharmaceutical companies generate extensive documentation, including standard operating procedures (SOPs), batch records, deviation reports, and validation protocols. AI tools can support document classification, version control, data extraction, and consistency checks, thereby reducing manual workload and minimizing human error (EMA, 2024).

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Machine learning models may also improve deviation and CAPA management by identifying recurring issues, root causes, and risk patterns. Intelligent systems can prioritize critical deviations based on severity and historical trends, supporting more efficient investigations and corrective actions (Bhosale et al., 2024).

Another important area is audit readiness and regulatory compliance. AI-powered platforms can continuously monitor compliance indicators and detect gaps related to GMP requirements, data integrity, and documentation completeness. Such systems may improve inspection preparedness and facilitate faster responses during regulatory audits (EMA, 2024).

Challenges and Regulatory Considerations

Despite the significant potential benefits, implementation of AI in pharmaceutical QA presents several challenges. Data quality and data integrity remain critical concerns, since AI systems depend on accurate, complete, and reliable datasets. Poor-quality data may lead to incorrect predictions and unreliable conclusions.

Another challenge is transparency and explainability of AI models. Regulatory authorities expect pharmaceutical companies to understand and justify decisions that may affect product quality and patient safety. Therefore, AI systems used in GMP environments should be validated, documented, and scientifically justified (EMA, 2024). Furthermore, Annex 22 is currently being prepared to regulate and provide guidance for the use of AI in GMP environments, including expectations for validation, data governance, and regulatory compliance. Additionally, the EU AI Act provides a regulatory framework ensuring that AI systems used in pharmaceutical quality systems are transparent, reliable, and aligned with data integrity and patient safety principles (European Parliament and Council of the European Union, 2024).

Cybersecurity and protection of confidential data are also important considerations. AI systems often require integration with multiple digital platforms, increasing the importance of secure data management and controlled user access.

Successful implementation of AI requires multidisciplinary collaboration between QA, IT, subject matter experts, data scientists, and regulatory experts.

Conclusion

Artificial Intelligence has the potential to transform pharmaceutical Quality Assurance by improving efficiency, supporting proactive quality management, enhancing compliance monitoring, and enabling advanced data analysis. AI-driven solutions can contribute to faster decision-making, reduction of manual activities, and improved risk management within pharmaceutical quality systems.

However, successful implementation requires careful validation, strong data governance, regulatory compliance, and adequate human oversight. AI should be considered as a supportive tool that complements QA professionals rather than replacing human judgment. Future development of regulatory frameworks and digital transformation strategies will further define the role of AI in pharmaceutical Quality Assurance.

References

Bhosale, A. et al., 2024. Exploring the Role of Artificial Intelligence in Modernizing Quality Assurance and Quality Control in the Pharmaceutical Sector. Int. J. Pharm. Sci. 2(11), 522-529. https://doi.org/10.5281/zenodo.14062391

European Medicines Agency (EMA), 2024. Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle. EMA/CHMP/CVMP/83833/2023. https://www.ema.europa.eu

European Parliament and Council of the European Union, 2024. Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act). Off. J. Eur. Union L 2024/1689. https://eur-lex.europa.eu/eli/reg/2024/1689/oj

Nakka, G. et al., 2026. Artificial intelligence in pharmaceutical manufacturing: Applications, case studies, and GxP implementation considerations. J. Pharm. Sci. 115(5), 104240. https://doi.org/10.1016/j.xphs.2026.104240