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Short communication

Artificial intelligence in pharmaceutical documentation: opportunities, challenges and regulatory compliance

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Introduction

Artificial intelligence (AI) is increasingly influencing pharmaceutical research, manufacturing, Quality Control laboratories and regulatory operations. Recent advances in generative AI, machine learning and natural language processing have improved documentation processes within pharmaceutical quality systems. Documentation is a critical component of GMP, GDP and regulatory compliance, providing evidence of product quality, process control and patient safety. In Quality Control laboratories, accurate and traceable documentation is essential for ensuring data reliability and compliance. Regulatory agencies increasingly recognize the potential of AI while emphasizing that implementation must remain consistent with quality risk management, validation and data integrity principles (FDA, 2023).

AI in pharmaceutical documentation and technical writing

Pharmaceutical organizations generate large volumes of controlled documents, including standard operating procedures, validation protocols, risk assessments, deviation investigations, change controls and regulatory submissions. AI-enabled tools can support drafting, summarization, terminology harmonization and document review (FDA, 2023).

Natural language processing can improve consistency and readability, while machine learning approaches can facilitate document classification and retrieval. Generative AI may accelerate preparation of first drafts and support knowledge management activities (EMA, 2024). According to current industry practice and FDA-regulated documentation principles, AI is most effective as an assistive technology rather than a replacement for qualified personnel (FDA, 2023).

Regulatory considerations and compliance requirements

The implementation of AI within regulated pharmaceutical environments requires careful consideration of regulatory expectations. FDA guidance, EMA reflection papers and international quality standards emphasize a risk-based approach to governance, transparency and lifecycle management (EMA, 2024). In the European Union, Regulation (EU) 2024/1689 (Artificial Intelligence Act) establishes harmonised rules (European Parliament and Council, 2024) for AI systems and introduces requirements related to risk management, technical documentation, human oversight, transparency, accuracy, robustness and cybersecurity. These

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principles complement existing pharmaceutical expectations for validated computerized systems and documented quality management processes (ICH, 2022).

In addition to GMP, GDP and computerized system validation requirements, pharmaceutical organizations operating within the European Union must consider the requirements of Regulation (EU) 2024/1689 (Artificial Intelligence Act). The Act establishes a risk-based framework for AI systems and introduces obligations related to risk management, technical documentation, transparency, record keeping, human oversight, accuracy, robustness and cybersecurity. Although many AI-supported technical writing applications may not fall within the high-risk category, organizations are expected to implement appropriate governance measures, ensure AI literacy among personnel and maintain adequate documentation demonstrating responsible AI deployment (European Parliament and Council, 2024).

Data integrity and governance

Data integrity remains a fundamental requirement for pharmaceutical quality systems. AI-supported processes should comply with ALCOA+ principles, ensuring that information remains attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring and available (ICH, 2023). Appropriate audit trails, access controls and version management are essential to preserve trust in AI-assisted documentation processes. Consistent with ICH Q9(R1), organizations should evaluate risks associated with incorrect outputs, cybersecurity vulnerabilities, confidentiality concerns and model drift (ICH, 2023).

Implementation framework

A structured implementation framework begins with identification of repetitive documentation activities that may benefit from AI assistance. Candidate solutions should be evaluated for validation capabilities, security and compatibility with existing quality systems. Pilot projects, training programs, governance procedures and continuous monitoring are necessary to ensure sustainable compliance. Human review and approval remain mandatory for all regulated content (FDA, 2023).

Conclusion

Artificial intelligence offers substantial opportunities to improve efficiency, consistency and knowledge management within pharmaceutical documentation systems. However, successful implementation requires validated systems, robust governance and continued human oversight. Alignment with GMP, GDP, ICH quality guidelines and Regulation (EU) 2024/1689 is essential (European Parliament and Council, 2024). Organizations that balance innovation with regulatory compliance can leverage AI to improve operational performance while maintaining product quality and patient safety (EMA, 2024).

Future implementation strategies should consider both FDA requirements and obligations arising from the EU Artificial Intelligence Act, which is becoming a key framework for trustworthy AI deployment in the pharmaceutical sector.

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