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Short communication

AI in manufacturing documentation: Ensuring data integrity

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Introduction

Pharmaceutical manufacturing documentation is essential for product quality, traceability, and data integrity in compliance with regulatory requirements (ICH, 2008; FDA, 2018; European Commission, 2011). In GMP environments, accurate, complete, contemporaneous, and consistent records support product lifecycle control and regulatory compliance. However, delayed entries, transcription errors, incomplete records, and inconsistencies may still occur despite established Good Documentation Practice principles (FDA, 2018). The increasing use of computerized systems and artificial intelligence (AI) creates opportunities to support documentation review through structured data capture, automated checks, anomaly detection, and identification of recurring documentation risks (Topol, 2019; Yu et al., 2018). Accordingly, the aim of this short communication is to provide a literature and regulatory framework-based overview of the potential role of AI in pharmaceutical manufacturing documentation, focusing on data accuracy, consistency, traceability, and integrity. Manufacturing Execution Systems (MES) are considered as a practical enabling layer for structured data capture and future compliant AI integration (European Commission, 2011; ISPE, 2022).

Materials and methods

Materials

This work was designed as a narrative review and conceptual regulatory analysis, not as an experimental comparative study. The analysis included regulatory and good practice documents relevant to pharmaceutical quality systems, computerized systems, electronic records, and data integrity: ICH Q10, FDA Data Integrity Guidance, EU GMP Annex 11, 21 CFR Part 11, and ISPE GAMP 5 (ICH, 2008; FDA, 2018; European Commission, 2011; FDA, 1997; ISPE, 2022). Scientific literature describing AI capabilities in data processing and healthcare-related applications was also reviewed (Topol, 2019; Yu et al., 2018).

Methods

A qualitative mapping approach was applied:

(1) identification of common documentation risks, including missing data, delayed entries, transcription errors, inconsistent entries, and insufficient traceability;

(2) mapping of AI-supportive functionalities, such as automated verification, anomaly detection, pattern recognition, and trend identification, to the

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identified risks; and (3) assessment of MES as an enabling digital environment for traceable, structured, and contemporaneous data capture. No experimental datasets or statistical comparison between non-AI and AI-supported processes were used; therefore, the outputs are presented as a structured conceptual synthesis.

Results and discussion

AI may support pharmaceutical manufacturing documentation through automated completeness and consistency checks, anomaly detection, and identification of recurring documentation errors. These functionalities may contribute to improved data integrity and facilitate documentation review processes (Topol, 2019; Yu et al., 2018). The effectiveness of such tools depends on the availability of structured and reliable data, in which Manufacturing Execution Systems (MES) provide an important foundation through standardized data capture, traceability, and audit trails (FDA, 2018; ISPE, 2022). However, AI implementation in GMP environments requires appropriate validation, risk management, data security, and human oversight. Therefore, AI should be considered a decision-support tool, while final review and approval of GMP- critical documentation must remain under human responsibility.

Conclusion

Artificial intelligence has significant potential to support pharmaceutical manufacturing documentation by improving data accuracy, consistency, traceability, and early detection of documentation risks. Nevertheless, implementation must remain aligned with validated computerized systems, data integrity principles, audit trail requirements, and applicable regulatory frameworks. MES represents a critical step toward digitalization, enabling structured data management and providing a compliant foundation for future AI integration. For GMP- critical documentation, AI should support, but not replace, qualified human review and approval.

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