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Short communication

Digitalization and artificial intelligence in pharmaceutical quality control laboratories

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Introduction

Pharmaceutical quality control (QC) laboratories generate data that support decisions on the identity, strength, purity, stability and compliance of medicines. As analytical procedures and data volumes increase, paper-based or only partly digitalized workflows become inadequate in terms of traceability, consistency and regulatory readiness. In this context, digitalization should be understood not merely as an information-technology upgrade, but as a systematic transformation of laboratory processes through integrated informatics platforms such as chromatography data systems (CDS), laboratory information management systems (LIMS) and electronic laboratory notebooks (ELN). Its main value lies in strengthening data integrity through ALCOA+ principles, audit trails, controlled access, validation of computerized systems and clearly defined procedures. Within this framework, artificial intelligence (AI) should be regarded as a selective supportive tool for data processing, trend analysis and resource optimization, rather than as a substitute for expert scientific judgement (Khaliq et al., 2025).

Pharma 4.0 and digitalization of QC laboratories

Pharma 4.0 provides a broader framework for integrating digital technologies, automation and interconnected data systems across pharmaceutical operations, including QC laboratories (Phiri et al., 2025). In this setting, digitalization is driven by increasing analytical complexity, expanding data volumes and the need for more efficient, traceable and compliant workflows (Hole et al., 2021; Khaliq et al., 2025). The QC laboratory may be viewed as an integrated system of inputs, processes and outputs, in which data represent both the product of laboratory activities and the basis for quality-related decisions. Digital transformation therefore depends on coordinated control of the data lifecycle through systems such as CDS, LIMS and ELN, combined with validated computerized systems, controlled access and audit trails in accordance with GxP expectations (Simonovski and Gjorgjeska, 2022).

Laboratory informatics platforms in QC: CDS, LIMS, and ELN

Laboratory informatics platforms constitute the operational backbone of digitalized QC laboratories by enabling controlled generation, processing, storage and retrieval of analytical and procedural data. CDS primarily support the acquisition, processing and review of chromatographic data, thereby reducing manual data handling and strengthening traceability of analytical results, whereas LIMS provide a broader framework for

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managing samples, specifications, test assignments, results, reagents and reporting workflows within a controlled digital environment (Hole et al., 2021; Khaliq et al., 2025; Simonovski and Gjorgjeska, 2022). ELN may further support structured documentation of selected laboratory activities. When appropriately configured, validated and integrated within the pharmaceutical quality system, these platforms provide the digital infrastructure necessary for reliable data lifecycle management, improved auditability and regulatory readiness.

Data integrity and supportive role of AI

In digitalized QC laboratories, the value of digital platforms depends on their ability to preserve data integrity throughout the data lifecycle. Data must be attributable, legible, contemporaneous, original and accurate, while ALCOA+ further requires completeness, consistency, endurance and availability. These principles are supported through validated systems, user-access controls, audit trails and procedural safeguards, all of which are essential for regulatory acceptability of analytical data (Charoo et al., 2023; European Commission, 2011). Within such a controlled environment, AI and machine learning (ML) may assist chromatographic data processing, signal interpretation, trend analysis and anomaly detection, thereby improving consistency when applied to structured and reliable data (Javid et al., 2025; Houhou and Bocklitz, 2021). However, their use must remain human-in-the-loop, with final interpretation and quality-relevant decisions retained by qualified personnel, in line with current expectations for context of use, monitoring and model control (Romero-Obon et al., 2025).

Conclusion

Digitalization of pharmaceutical QC laboratories represents a systemic transformation of laboratory operations rather than a simple technological upgrade. Through the implementation of informatics platforms, supported by robust data integrity principles and validated computerized systems, digitalization can enhance traceability, consistency, auditability and regulatory readiness. Within this framework, AI and ML are best regarded as selective supportive tools whose value depends on structured data, defined context of use and sustained human expert oversight. Looking ahead, the maturation of interoperable, AI-ready data infrastructures and the emergence of dedicated regulatory frameworks for AI in GxP environments are expected to shape the next phase of laboratory digitalization. The future of QC laboratories therefore lies in the responsible integration of digital systems and advanced analytics within a robust pharmaceutical quality system.

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