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Short communication

The impact of digitalisation on batch release in the pharmaceutical industry

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Introduction

Digitalisation in batch release can reduce delays caused by fragmented records and manual reconciliation by providing timely, traceable access to manufacturing and quality data and enabling review by exception without weakening GMP oversight (Fitzgerald et al., 2025; Lencastre and Neto, 2024). Regulatory requirements call for validated computerised systems with lifecycle control, data integrity, audit trails, and reliable electronic records and signatures where needed (EC, 2011; U.S. FDA, 2026). This paper therefore focuses on MES as the main system for real-time manufacturing control, supported by SAP integration and DMS governance. eBR is treated as a future step, while AI is limited to review support under continuous human oversight and GMP guidance (EMA, 2026; EFPIA, 2024).

Materials and methods

This study uses a narrative review of scientific and technical literature on digitalisation and change management, supported by a focused review of key regulatory texts relevant to batch release. These include EU GMP Annex 11 and Annex 16, FDA 21 CFR Part 11, EAEU GMP Decision No. 77, and recent guidance on AI governance in the medicines lifecycle. The analysis identifies digital capabilities relevant to batch release, groups them into a site-relevant technology stack centred on MES with SAP integration and DMS controls, and maps them to key regulatory control areas, including validation, audit trails, access control, data integrity, and lifecycle governance

Results and discussion

Digitalisation in batch release means creating a controlled and connected environment where the system checks completeness, records metadata such as who did something, when, and why, and supports risk-based review (Lencastre and Neto, 2024). In practice, this digital ecosystem depends on reliable manufacturing data from MES, controlled documents in a DMS, and strong integration with enterprise systems such as SAP. Together, these elements provide traceable evidence for QA/QP review (EC, 2011; Lencastre and Neto, 2024).

Manufacturing Execution System (MES)

MES is a key digital system in pharmaceutical manufacturing that supports real-time control of production activities. It links equipment and process data to each batch and guides work through fixed workflows, parameter limits, and full traceability of materials and processes (Fitzgerald et al., 2025). MES

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also gives real-time visibility across production steps, helping teams detect deviations, interruptions, and unusual trends more quickly. This supports faster deviation management, root-cause analysis, and better QP awareness during batch release (Fitzgerald et al., 2025; Lencastre and Neto, 2024). In addition, dashboards and statistical tools support continuous monitoring, trend analysis, and process improvement. MES also supports compliance with EU GMP Annex 11 through validated operation, data integrity, audit trails, and access control (EC, 2011). DMS strengthens document control, while SAP–MES integration improves end-to-end traceability and supports reliable quality decisions. AI is used only as a support tool to prioritise exceptions, identify unusual patterns, and speed up review preparation under QA/QP responsibility and human oversight. (EMA, 2026).

Challenges

Implementation can be challenging because of validation requirements, risks to data integrity and cybersecurity, the complexity of MES – SAP integration, and the need for effective change management. These challenges should be managed through a lifecycle approach and risk-based controls in line with Annex 11 and related guidance (EC, 2011; EC, 2025; Lencastre and Neto, 2024; U.S. FDA, 2025).

Conclusion

In conclusion, digitalisation can improve batch release by increasing efficiency, strengthening compliance, and supporting robust data-driven oversight. MES is central to this development because it provides real-time visibility, structured process execution, and traceable evidence for QA/QP review in line with GMP requirements. At Alkaloid AD Skopje, the implementation of digital systems, especially MES, indicates progress toward greater digital maturity, stronger data integrity, and better process understanding. Although more operational cycles are needed for stronger trend analysis, current results are promising. Further MES-SAP integration and carefully governed AI use may strengthen inspection readiness and improve the reliability of batch release decisions.

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