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Short communication

The Qualified Person as a data-driven and human-in-the-loop decision-maker

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Introduction

Digital transformation is reshaping pharmaceutical manufacturing, quality control, and batch release. In this environment, Qualified Person (QP) remains the individual with final professional and legal responsibility for certification and release of medicinal product batches. Annex 16 defines QP certification as a formal and personal act and requires confirmation that each batch has been manufactured and checked in accordance with GMP, the marketing authorisation, and applicable legal requirements (European Commission, 2015).

The QP Code of Practice complements this requirement by emphasizing independence, personal responsibility, professional judgement, oversight, and justified reliance on other people and systems (ECA Foundation, 2023). These principles are increasingly important because pharmaceutical operations now depend on electronic batch records, integrated quality systems, and global data flows rather than only on paper documentation. At the same time, Pharma 4.0 has introduced interconnected systems, real-time monitoring, and improved process transparency, moving the QP toward a more data-driven role (ISPE, n.d.; ISPE Pharma 4.0 Plug & Produce Working Group, 2024). Recent literature further suggests a transition toward a more human-centered Pharma 5.0 model, where artificial intelligence (AI) and predictive analytics support but do not replace expert judgement (Romero-Obon et al., 2025; Suriyaamporn et al., 2024).

Materials and methods

This short paper was prepared as a review of current regulatory and scientific literature relevant to QP role in the digital era. The main regulatory sources were Annex 16 of the EU GMP and QP Code of Practice (ECA Foundation, 2023). To frame digital transformation in pharmaceutical manufacturing, key ISPE publications on Pharma 4.0 and smart manufacturing were also reviewed (ISPE, n.d.; ISPE Pharma 4.0 Plug & Produce Working Group, 2024). In addition, recent review articles addressing AI integration and human-in-the-loop concepts in pharmaceutical development and ongoing process verification were considered (Romero-Obon et al., 2025; Suriyaamporn et al., 2024). The sources were analyzed with focus on three dimensions of QP practice: trust in electronic data and computerized systems, the balance between justified reliance and non-delegable personal responsibility, and the conditions under which remote oversight can support certification decisions.

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Results and discussion

The reviewed literature shows that one of the main challenges for the modern QP is growing reliance on electronic data generated by eQMS, LIMS, MES, electronic batch records, cloud platforms, and advanced analytics tools. Digitalization improves traceability, data availability, and process understanding, but it also introduces risks related to data integrity, weak audit trails, inconsistent data structures, and legacy system integration (Suriyaamporn et al., 2024; ISPE Pharma 4.0 Plug & Produce Working Group, 2024). Therefore, QP confidence in system outputs cannot be passive; it must be based on understanding of system validation, access control, data governance, and intended use, in line with Annex 16 expectations (European Commission, 2015).

A second challenge is the balance between reliance and responsibility. Both Annex 16 and QP Code of Practice allow QP to rely on the work of qualified functions and appropriately controlled systems, but they do not allow delegation of ultimate certification responsibility (European Commission, 2015; ECA Foundation, 2023). In digital environments, release decisions may be influenced by dashboards, automated alerts, and predictive analyses. As a result, QP must understand not only GMP and quality systems, but also the strengths and limitations of software-enabled decision support. Technology can strengthen oversight, but it must not replace independent professional judgement.

The literature also supports a shift from a purely data-driven QP role in Pharma 4.0 toward a human-in-the-loop authority in Pharma 5.0. AI-based tools may accelerate trend detection, improve process monitoring, and support proactive risk management, yet scientific interpretation, ethical oversight, and regulatory accountability remain human responsibilities (ISPE, n.d.; Suriyaamporn et al., 2024; Romero-Obon et al., 2025). This is particularly relevant for remote oversight and remote batch certification. Although Annex 16 does not explicitly define remote certification, it requires sufficient oversight of manufacturing, testing, deviations, and other critical quality information before certification (European Commission, 2015). Overall, digital transformation does not simplify the QP role; rather, it expands the competence profile required for certification by adding stronger expectations in data integrity, computerized system oversight, and digital literacy.

Conclusion

The role of Qualified Person is becoming more complex in the digital era. Although digital systems and AI-supported tools improve access to information and process oversight, they do not reduce QP's personal responsibility for batch certification and release (European Commission, 2015; ECA Foundation, 2023).

Within Pharma 4.0 and the emerging Pharma 5.0 model, QP is evolving into a data-driven, human-in-the-loop decision-maker who must combine GMP expertise with digital competence, critical thinking, and oversight of computerized systems in order to protect product quality and patient safety (ISPE, n.d.; Romero-Obon et al., 2025; Suriyaamporn et al., 2024).

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