

Peer Review

Review of: "Ensuring Quality in Clinical Research: The Impact of Quality Assurance and Quality Control in the Field of Good Clinical Practice"

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This review provides a comprehensive and informative overview of the role of quality assurance (QA) and quality control (QC) within Good Clinical Practice (GCP) frameworks, successfully integrating historical ethical foundations, regulatory evolution, and contemporary inspection findings from major agencies such as the FDA, EMA, and MHRA. The manuscript is well-structured and offers valuable educational insights for investigators, quality professionals, and ethics committee members, particularly through its detailed description of investigator responsibilities, data integrity principles (e.g., ALCOA-C), and real-world examples of regulatory deficiencies. However, the article would benefit from enhanced critical synthesis rather than predominantly descriptive reporting of guidelines and inspection summaries. The review lacks methodological transparency regarding the literature search strategy, inclusion criteria, and evidence appraisal, which limits reproducibility and the scientific rigor expected from modern narrative or systematic reviews. Additionally, the manuscript could be strengthened by integrating comparative analysis of QA/QC effectiveness, quantitative outcomes demonstrating the impact of quality systems on trial performance, and emerging challenges such as decentralized trials, artificial intelligence-assisted monitoring, and digital data governance. The discussion would also benefit from a clearer distinction between QA and QC operational roles and a stronger global perspective beyond regional regulatory examples. Minor improvements in language clarity, reduction of repetitive regulatory descriptions, and incorporation of graphical frameworks summarizing quality management workflows could further enhance readability and impact. Overall, the article represents a valuable educational resource but would gain greater scholarly strength through methodological clarification and deeper analytical interpretation of current quality management trends in clinical research.

Declarations

Potential competing interests: No potential competing interests to declare.