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Quality Risk Management and Process Control

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Abstract: *Quality Risk Management (QRM) is a systematic process for identifying, evaluating, and controlling risks to product quality and patient safety in compliance with regulatory standards such as ICH Q9. In the pharmaceutical industry, QRM is essential for decision-making, process optimization, and maintaining regulatory compliance. However, its practical implementation faces several challenges, including inadequate training, inconsistent application across departments, insufficient and unreliable data, subjective risk scoring, and limited integration with Quality Management Systems (QMS). Organizational resistance, resource constraints, and varying expectations of global regulatory agencies further complicate the process. These issues can result in incomplete risk assessments, delayed mitigation measures, and reduced overall effectiveness of QRM frameworks. Addressing these challenges requires strong management commitment, harmonized procedures, regular training, and effective integration of QRM with QMS elements such as CAPA, deviation management, and change control. A proactive, data-driven, and continuously reviewed QRM system can transform risk management from a regulatory obligation into a strategic tool for quality improvement, efficiency, and patient safety. This review highlights key barriers in QRM and emphasizes the importance of targeted strategies to enhance its effectiveness and long-term sustainability in pharmaceutical quality assurance*

Keywords: Quality Risk Management, QRM challenges, pharmaceutical quality, ICH Q9, risk assessment, process control, quality management system, patient safety