

WHO QUALITY RISK MANAGEMENT-2003 VERSUS QRM
2026
HEALTHCARE INDUSTRY

<i>Report Description</i>	WHO QUALITY RISK MANAGEMENT-2003 VERSUS QRM 2026
<i>Industry Type</i>	Healthcare Industry
<i>Document Type</i>	Pre-audit record
<i>Summary of changes</i>	The WHO Quality Risk Management (QRM) Guideline 2026 expands and modernizes the 2003 framework by strengthening lifecycle-based risk management, governance, knowledge management, subjectivity control, documentation practices, risk-based decision-making, and regulatory oversight. While many foundational principles remain aligned, the 2026 edition introduces several new requirements and enhanced expectations that require updates to existing QRM procedures, risk assessment methodologies, training programs, and quality systems. The major gaps requiring action are summarized below.

Disclaimer:

This document has been prepared as an independent gap assessment and impact analysis based on a review of applicable standard requirements and generally accepted industry practices at the time of preparation. Referenced ISO standards remain copyrighted property of ISO.

This assessment is intended solely for internal quality planning, risk evaluation, and audit readiness purposes. It does not constitute certification, audit, regulatory approval, or a declaration of compliance with any ISO or other industrial standard.

Responsibility for implementation of recommended actions and for achieving and maintaining compliance with applicable standards and regulatory requirements remains with the organization.

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1.0. Comparison Table:

Below Table describes the alignment clause-by-clause between the two versions of the ISO standard, which can be fully aligned (**Full**) or partially aligned (**Part**) or not aligned (**Not**).

2026 Clause	Requirement	OLD Clause	Requirement	Alignm ent	Remarks
3 Quality risk management process 3.1 Initiating a QRM process	The 2026 version emphasizes a structured and systematic approach to Quality Risk Management (QRM) to support science-based decision-making. It highlights the importance of clearly defining the risk question, gathering relevant information and data, assigning appropriate leadership and resources, and establishing timelines and expected outputs. The guidance also underscores the role of internal procedures in defining governance arrangements, stakeholder involvement, and responsibilities to ensure effective planning and execution of the risk management process.	3.1 Initiating a QRM process	The 2003 version promotes the use of a structured Quality Risk Management (QRM) process to support informed, science-based decision-making. It outlines key planning elements such as defining the risk issue, collecting relevant background information, assigning leadership and resources, and establishing timelines and decision-making expectations. The guidance also recognizes the importance of documented procedures in clarifying process steps, stakeholder involvement, and organizational responsibilities for effective risk management.	Full	2026 (3.1) restates OLD with no change to intent or parameter values
3.2 Personnel involved in QRM	The 2026 version places greater emphasis on organizational responsibility, competency, and governance in Quality Risk Management (QRM). It highlights the need for personnel with appropriate expertise, supported by multidisciplinary teams and senior management involvement, to ensure effective execution of risk management activities. The guidance also outlines the key competencies required for risk assessment, evaluation, control, monitoring, and review, while reinforcing the importance of documenting QRM activities to support consistency, traceability, and informed decision-making throughout the product lifecycle.	3.2 Personnel involved in QRM	The 2003 version emphasizes the importance of assigning suitably qualified personnel to Quality Risk Management (QRM) activities, with multidisciplinary teams identified as a practical means of ensuring adequate expertise. It focuses on the competencies needed to perform risk analysis, evaluate and control risks, monitor outcomes, and assess the broader impact of risk findings on related products and processes. The guidance also highlights the need for QRM activities to be clearly defined and documented to support effective and consistent risk management practices.	Part	2026 (3.2) adds the requirement for personnel to 'identify hazards and analyse their potential risks' while OLD required only 'identify and analyse potential risks'
3.3 Knowledge of the product and process	The 2026 version emphasizes that Quality Risk Management (QRM) should be grounded in product and process knowledge throughout the product lifecycle. It highlights the value of using process flow diagrams to visualize operations, controls, and interactions between process	3.3 Knowledge of the product and process	The 2003 version emphasizes that Quality Risk Management (QRM) should be founded on an understanding of the product and its associated processes throughout the product lifecycle. It highlights the usefulness of process flow diagrams in providing a clear representation of operations	Part	2026 (3.3) adds a reference to section 3.9 on managing subjectivity in QRM activities, which is absent in OLD; both versions require QRM to be based on product knowledge according to the product life-cycle stage and suggest using flow diagrams for process evaluation.

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2026 Clause	Requirement	OLD Clause	Requirement	Alignm ent	Remarks
	steps, supporting a more comprehensive assessment of risks. The guidance also draws attention to the importance of managing subjectivity in risk evaluations, maintaining documented updates to process representations, and leveraging knowledge management principles, consistent with broader pharmaceutical quality system practices.		and controls, enabling a broader assessment of how individual process steps interact. The guidance also recognizes the importance of considering upstream and downstream activities and maintaining documentation when process representations are updated.		
3.4 Risk assessment	The 2026 version significantly expands the guidance on risk assessment by emphasizing a holistic evaluation of product quality, safety, and efficacy. It promotes a systematic approach to identifying, analyzing, evaluating, and controlling risks across all aspects of the product lifecycle, including materials, processes, facilities, equipment, personnel, and the supply chain. The guidance provides greater detail on risk assessment methodologies, the use of decision trees and risk matrices, and the importance of documenting risk ratings and their rationale. It also places increased emphasis on managing subjectivity through evidence-based evaluations, considering existing controls and their effectiveness, maintaining risk assessment records, and proactively eliminating or reducing risks to protect product quality and patient safety.	3.4 Risk assessment	The 2003 version outlines a structured approach to risk assessment within Quality Risk Management (QRM), emphasizing the identification, evaluation, and control of risks that may affect product quality, safety, and efficacy. It highlights the use of risk assessment tools, documented decision-making, and risk-based controls across products, processes, facilities, personnel, and supply chains, while reinforcing the importance of maintaining patient safety and product quality through proactive risk reduction and continuous oversight.	Part	2026 (3.4) expands risk assessment by requiring assessment of environment and reagents, mandates evaluation of control effectiveness and impact on consequence, probability, detectability, and updates terminology to 'manufacturers' and 'proactively.' OLD (3.4) lacked environment/reagent assessment, control-effectiveness mandate, and used different terminology and risk-list categories.
3.5 Risk control	The 2026 version expands the discussion on risk control by describing it as a structured decision-making process focused on reducing, eliminating, accepting, or managing risks to acceptable levels. It provides broader coverage of risk treatment options, emphasizes the role of risk controls in supporting process monitoring, qualification, and validation activities, and highlights the importance of documentation, periodic review, and predefined	3.5 Risk control	The 2003 version describes risk control as a key component of Quality Risk Management (QRM), focusing on the evaluation and implementation of measures to reduce, accept, or manage identified risks. It highlights the use of appropriate control strategies, documentation, periodic review, and corrective actions to maintain risks at acceptable levels. The guidance also emphasizes the importance of defining responsibilities, monitoring the effectiveness of controls,	Part	2026 (3.5) expands OLD (3.5) by clarifying that taking the risk may occur to follow an opportunity, or when no controls are available or controls do not sufficiently modify the risk, whereas OLD simply listed 'taking the risk' without these conditions; all other requirements and examples remain unchanged.