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Quality Risk Management In The Pharmaceutical Industry: A Literature Review

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Abstract

Quality Risk Management (QRM) is increasingly recognized as a critical framework for ensuring pharmaceutical product quality, safety, and regulatory compliance throughout the product lifecycle. This literature review aimed to examine the implementation of QRM in the pharmaceutical industry, with a particular focus on its role in preventing deviations and quality failures. A total of 25 scientific articles published between 2020 and 2026 were systematically collected and analysed from databases including Google Scholar, ScienceDirect, PubMed, and ResearchGate using predefined inclusion and exclusion criteria. The results indicate that QRM tools — particularly Failure Mode and Effect Analysis (FMEA), Corrective and Preventive Action (CAPA), Quality by Design (QbD), and risk matrices — are widely applied across manufacturing, supply chain, warehousing, packaging, and distribution processes. FMEA was identified as the most prevalent risk assessment method, while integrated CAPA systems have demonstrably shifted quality management from a reactive to a proactive paradigm. Challenges including subjectivity in risk scoring, limited training, and suboptimal integration with quality management systems remain prevalent. This review concludes that comprehensive QRM implementation significantly reduces the frequency of deviations, strengthens GMP compliance, and enhances patient safety in the pharmaceutical industry.

Keywords: ***Quality Risk Management, Deviation Prevention, GMP Compliance, CAPA, Pharmaceutical Industry***

INTRODUCTION

The safety and quality of pharmaceutical products are fundamental aspects of public health protection, as every medicinal product must meet established standards of safety, efficacy and quality. Quality failures in pharmaceutical products can have serious consequences, ranging from financial losses for companies to risks to patient safety due to contamination, incorrect levels of active ingredients, or product instability. According to a report by the United States Food and Drug Administration, the majority of product recalls between 2020 and 2023 were caused by non-compliance with Good Manufacturing Practice (GMP), particularly regarding documentation, process control, and contamination (FDA, 2023; (Haddad & Greene, 2020). In Indonesia, the Food and Drug Supervisory Agency also reported that deviations in production processes and weaknesses in quality systems remain the dominant findings in Cara Pembuataan Obat yang Benar (BPOM, 2023).

The increasing complexity of pharmaceutical manufacturing processes is driving the adoption of a more proactive quality management approach through Quality Risk Management (QRM). QRM is a systematic process for identifying, analysing, evaluating, controlling and reviewing quality risks in pharmaceutical products throughout the product lifecycle (ICH, 2023). The implementation of QRM based on the ICH Q9 and ICH Q9 (R1) guidelines is considered capable of enhancing the effectiveness of the quality system, strengthening Corrective and Preventive Actio, and reducing the frequency of deviations and quality failures in the pharmaceutical industry (Prajapati *et al*., 2021;Kendrick *et al*., 2024). QRM is also integrated with ICH Q8 and ICH Q10 in establishing a comprehensive, risk-based Pharmaceutical Quality System (ICH, 2015 ;Haddad & Greene, 2019).

Despite the ongoing development of research on QRM, the majority of studies still focus on specific aspects such as process validation, environmental control, or the investigation of deviations; consequently, they have not yet provided a comprehensive picture of the effectiveness of QRM implementation in preventing deviations and quality failures in the pharmaceutical industry. Furthermore, research on the implementation of QRM in developing countries, including Indonesia, remains limited (Qiu *et al*., 2024). Therefore, a literature review is required to examine various

scientific publications on the implementation of Quality Risk Management in the pharmaceutical industry, particularly regarding risk assessment methods, causes of deviations, and strategies for preventing quality failures.

In response to these issues, this literature review aims to examine scientific publications from 2020 to 2026 concerning the implementation of Quality Risk Management in the pharmaceutical industry, with a focus on the prevention of deviations and quality failures. This review is expected to provide an overview of the effectiveness of QRM implementation and serve as a reference for regulators, academics, and the pharmaceutical industry in improving risk-based quality management systems (Waghule *et al*., 2021; Qiu *et al*., 2024).

RESEARCH METHODS

The research method employed in this study was a systematic review, involving the collection and analysis of 30 relevant scientific articles on the application of Quality Risk Management (QRM) in the prevention of deviations and quality failures in the pharmaceutical industry. Articles were obtained through a literature search across various scientific databases, such as Google Scholar, ScienceDirect, PubMed, and ResearchGate, using the keywords "Quality Risk Management", "deviations", "quality failures", and "pharmaceutical industry". Article selection was based on predefined inclusion and exclusion criteria, including topic relevance, year of publication, and availability of full-text articles. The data obtained were then analysed descriptively to identify the application of QRM in minimising the risk of deviations and maintaining the quality of pharmaceutical products.

RESULTS AND DISCUSSION

Based on a review of 25 articles, Quality Risk Management (QRM) is widely used as a systematic approach to identifying, analysing, evaluating, controlling, communicating and reviewing quality risks in the pharmaceutical industry. The reviewed articles indicate that tools such as FMEA, Risk Matrix, CAPA, QbD, HACCP, FTA, RPN, ISO 31000, and digital approaches can be used to prevent deviations, contamination, CAPA delays, batch failures, quality non-conformities, and risks in the supply chain. The results of this review are presented in Table 1.

Table 1. Results of the Paper Review

No.	Author (Year)	Research Objectives	Methods/ QRM Instruments	Key Findings	Contributions to the Prevention of Deviations/Quality Failures
1.	Titapiwatanakun *et al.* (2023)	Assessing the risks of GMP inspections of overseas manufacturers based on desktop inspections	ICH Q9, FMEA, RPN	The high risk stems from the document inspection process and the lack of a phased approach	Strengthening GMP assessments and reducing quality gaps in inspections
2.	Mashingia *et al*. (2025)	Evaluating the performance of joint GMP inspections within the EAC	GMP evaluation, CAPA, timeline analysis	Some facilities comply with GMP, but there are delays in CAPA	Helping to improve regulatory oversight and the follow-up of non-conformities
3.	Arunagiri *et al*. (2024)	Reviewing CAPA within the pharmaceutical quality system	CAPA, RCA, 8D methodology	CAPA is encouraging a shift from a reactive to a proactive approach	Preventing the recurrence of deviations by addressing the root causes and

					implementing preventive measures
4.	Cheptanari-birta & Adauji (2025)	Assessing risks in pharmaceutical services	Delphi, Ishikawa, Risk Matrix	56 potential causes of medication errors have been identified	Shows that risk mapping can prevent process errors
5.	Laxmi *et al*. (2025)	Examining the evolution of deviations and CAPA in API manufacturing	Deviation management, CAPA, digitalization	Digitalisation, AI and blockchain support proactive CAPA	Expediting investigations into deviations and API quality control
6.	Galvão *et al*. (2025)	Examining the application of QbD in the pharmaceutical industry	QbD, CQA, CPP, FMEA, HACCP	QbD reduces batch-to-batch variation and the risk of product recalls	Preventing quality failures right from the product development stage
7.	Alsaidalani (2022)	Assessing the risks associated with the filling and handling of sterile products	ICH Q9, FMEA, RPN	Critical risks are identified and managed through mitigation measures	Preventing contamination and quality failures in sterile products
8.	Ismael & Ahmed (2020)	Implementing QRM in pharmaceutical production processes	FMEA, QRM process	QRM reduces risk and improves production processes	Helping the industry identify critical points and manage risks
9.	Harsanti & Chaerunisaa (2021)	An overview of QRM methods and their application in the pharmaceutical industry	Literature review, ICH Q9, FMEA, HACCP	QRM comprises risk assessment, risk control, risk communication and risk review	Serving as the conceptual basis for quality risk prevention throughout the product lifecycle
10.	Achyar *et al*. (2024)	Identifying operational risks in the pharmaceutical raw materials industry	ISO 31000, risk matrix	17 operational risks were identified, including extreme and high risks	Helping to prioritise operational risk mitigation measures that impact quality
11.	Yang *et al*. (2025)	An Overview of QbD: From Concept to Industrial Application	QbD, DoE, FMEA, PAT, AI, digital twin	QbD reduces batch failures and improves process robustness	Supporting design-based quality control and real-time monitoring
12.	Vyawhare (2025)	Developing an FMEA approach for new product introduction	FMEA, RPN, QRA, regulatory alignment	FMEA helps to identify risks associated with scale-up, method transfer, raw materials, cleaning and distribution	Preventing deviations during the transition of a product from development to commercial scale
13.	Khan *et al*. (2024)	An overview of deviations, OOS and CAPA in the pharmaceutical industry	Deviation handling, OOS, CAPA	Deviations must be reported, investigated and corrected immediately through CAPA	Strengthening root-cause investigations and preventing recurrence
14.	Qiu *et al*., (2024)	Assessing the effectiveness of QRM in PIVAS	FMEA, Risk Matrix, KPI	Medication errors have decreased, preparation times have been reduced, and staff satisfaction has increased	Demonstrating that QRM can improve safety and efficiency in sterile pharmaceutical processes

15.	Alsaidalani (2022)	Analysing QRM in the supply chain, warehouse and dispensing	ICH Q9, FMEA	Implementing QRM at the early stages of production helps to prevent complaints and delays in the process	Preventing quality risks from the procurement, storage and weighing of materials
16.	Fazila *et al*. (2025)	Analysing supplier qualification risks in the pharmaceutical industry	Risk mitigation, auditing, supplier diversification	The main risks include quality, compliance and supply disruptions	Strengthening the supply chain to ensure the quality of materials and the sustainability of production
17.	Ilmu *et al*. (2024)	Assessing the risks associated with the storage and distribution of raw materials	FMEA, RPN	15 risks were identified, including high and very high-risk categories	Helping to manage warehouse risks to ensure that product quality, safety and efficacy are maintained
18.	Ramhari *et al*. (2024)	An overview of risk assessment tools in quality assurance	FMEA, HACCP, FTA, Risk Ranking	QRM can be applied to manufacturing, distribution, inspection and product review	Providing a range of risk analysis tools to prevent a decline in product quality
19.	Komal *et al*. (2025)	An overview of QRM and process control in pharmaceutical quality	FMEA, HACCP, FTA, SPC, PAT	The integration of QRM and process control supports the management of CPP and CQA	Preventing process variations and quality failures through continuous process control
20.	Azzahra *et al*. (2024)	Assessing the risk of cross-contamination in the packaging area	FMEA, RPN	19 cross-contamination risks have been identified, ranging from low to very high	Helps prevent cross-contamination and ensure product safety
21.	Khan *et al*. (2020)	An overview of QRM principles and tools in the pharmaceutical industry	QRM tools, FMEA, HACCP, FTA	QRM is applied to development, manufacturing, distribution, inspection and review	Serving as the basis for the implementation of QRM for deviation control, complaints, batch failures and investigations
22.	Sharma *et al*. (2020)	Examining the impact of QRM on reducing non-conformities	QRM process, risk assessment tools	QRM helps companies and regulators assess, manage and review risks	Reducing quality discrepancies through risk-based decision-making
23.	Elmadhoun *et al*. (2025)	Analysing QRM in the final stages of sterile product manufacturing	ICH Q9, FMEA, RPN	Risks associated with sterilisation, inspection, labelling, packaging and storage can be controlled	Preventing labelling errors, contamination, defective products passing inspection, and uncontrolled storage
24.	Pujari (2026)	Developing modern deviation and CAPA strategies in PQS	Risk-based, data-driven CAPA, narrative synthesis	Deviations are viewed as process indicators, not merely administrative matters	Strengthening investigations, containment, the effectiveness of corrective and preventive actions (CAPA), and the prevention of recurring non-conformities
25.	Tharun *et al*., (2026)	Exploring best practices in QRM for patient safety	ICH Q9/Q10, FMEA, FTA, HACCP, Pharma 4.0	QRM supports GMP, PQS, lifecycle management and quality digitalisation	Emphasising QRM as a strategy for preventing deviations, recalls and quality failures

An Overview of Quality Risk Management in the Pharmaceutical Industry

Quality Risk Management (QRM) is a systematic approach within the pharmaceutical industry to identify, assess, control, communicate and review risks that may affect product quality. Based on a review of 25 articles, QRM is not only used during the production stage, but also in product development, raw material procurement, storage, distribution, inspection and post-production evaluation. According to Khan *et al*. (2020), QRM is an essential component of the quality system as it helps maintain product quality throughout the entire lifecycle of a medicinal product. Consequently, QRM serves as the foundation for risk-based decision-making to ensure that the quality, safety, and efficacy of the product remain assured.

The concept of QRM in the pharmaceutical industry largely refers to the ICH Q9 guideline, which emphasises that risk assessment must be based on scientific knowledge and directly relate to patient safety. According to Ramhari *et al*. (2024), QRM comprises four main components: risk assessment, risk control, risk communication, and risk review. These four components form a workflow that helps the industry manage risks in a structured manner, from the identification of potential hazards to the evaluation of the effectiveness of controls. Therefore, QRM serves not only as a regulatory requirement but also as a strategy for continuous quality improvement.

In modern pharmaceutical quality systems, QRM is integrated with Good Manufacturing Practices (GMP), the Pharmaceutical Quality System (PQS), CAPA, process validation, audits, and change control. According to Tharun *et al*. (2026), QRM supports the integration of ICH Q9/Q10, GMP, and product lifecycle management to ensure quality and patient safety. This integration is crucial because quality deviations and failures are often not isolated incidents but are linked to processes, people, equipment, documentation, and suppliers. Through a QRM approach, the industry can identify the highest-risk areas and prioritise preventive actions before issues escalate into quality failures.

Factors Contributing to Deviations and Quality Failures in the Pharmaceutical Industry

Deviations in the pharmaceutical industry can occur when a process deviates from approved procedures, standards, specifications or work instructions. The findings of the review indicate that the causes of deviations generally stem from human factors, working methods, machinery, materials, the environment and documentation systems. According to Khan *et al*. (2020), deviations can arise during production, testing, sampling, storage, or distribution, and must therefore be reported and investigated immediately. If deviations are not handled appropriately, the risk of batch failure, out-of-specification (OOS) results, contamination, and products failing to meet specifications may increase.

Human factors, or human error, are a key cause of deviations, as pharmaceutical processes rely heavily on the precision of operators, analysts, supervisors, and QA personnel. Errors may include failure to follow SOPs, recording errors, lack of training, misinterpretation of work instructions, or failure to perform double-checks. According to Cheptanari-birta & Adauji (2025), staff fatigue, multitasking, lack of knowledge, and errors in prescriptions or documentation are risk factors that can trigger process errors. This indicates that risk control is not sufficient with SOPs alone, but also requires training, supervision, and a strong quality culture.

In addition to human factors, quality failures can also stem from raw materials and suppliers that are not properly qualified. According to Fazila *et al*. (2025), risks associated with supplier qualification include quality risks, compliance risks, and supply disruptions that can affect the continuity of production. Raw materials that do not meet specifications can cause production processes to be disrupted, result in inconsistent end products, or even lead to batches being rejected. Therefore, QRM in the supply chain is essential to ensure suppliers meet quality standards, regulations, and supply reliability.

Another risk that frequently leads to quality failures is uncontrolled storage and distribution of materials. According to Ilmu *et al*. (2024), the storage and distribution of raw materials in pharmaceutical warehouses can pose risks that affect product quality, safety, and efficacy. These risks may include incorrect placement of materials, inappropriate temperature or humidity conditions, errors

in material handover, and delays in internal distribution. If these risks are not controlled, the quality of materials entering the production process may decline, thereby impacting the quality of the final product.

The Implementation of QRM in Deviation Prevention

The implementation of QRM in the prevention of deviations begins with the identification of risks at each stage of the process that could potentially lead to deviations. This stage aims to answer key questions such as what could go wrong, how likely it is to occur, and how serious the impact on product quality would be. According to Khan *et al*. (2020), the risk assessment process begins with hazard identification, risk analysis, and risk evaluation based on the level of likelihood, severity, and detectability. In this way, industries can prioritise risks and determine the most appropriate control measures.

The most widely used method in the reviewed articles is Failure Mode and Effects Analysis (FMEA). FMEA is used to identify failure modes, causes of failure, impacts on the product, and risk levels based on the Risk Priority Number (RPN) value. According to Azzahra *et al*. (2024), FMEA is effective for assessing cross-contamination risks as it is able to categorise risks into low, medium, high, and very high categories. Through this categorisation, the industry can prioritise risks that require immediate control measures.

In the packaging area, QRM plays a vital role because labelling errors, product mix-ups and cross-contamination can have a direct impact on patient safety. Research by Azzahra *et al*. (2024) shows that the risk of cross-contamination in the packaging area can originate from previous products, other production areas, or particles from machinery and equipment. These risks must be controlled through facility design, personnel and material flow, cleaning procedures, and adequate segregation of work areas. Thus, QRM helps ensure that packaging activities do not become a source of quality failure.

In the GMP inspection process, QRM can be used to assess the reliability of the inspection system, particularly when inspections are document-based. According to Titapiwatanakun *et al*. (2023), the FMEA approach to desktop inspection helps identify risk gaps in the GMP inspections of overseas pharmaceutical manufacturers. High risks were found in document inspection processes that lacked a step-by-step approach and adequate evaluation. This indicates that QRM applies not only to production processes but also to regulatory and quality assurance activities.

The Role of CAPA in Preventing Recurring Deviations

Corrective and Preventive Action (CAPA) is a vital component of QRM as it serves to rectify problems that have already occurred whilst preventing similar issues from recurring. Effective CAPA must begin with an investigation into the root cause, rather than merely addressing the symptoms or immediate consequences of a deviation. According to Arunagiri *et al*. (2024), CAPA has a dual approach: corrective actions to address current non-conformities and preventive actions to prevent recurrence. Thus, CAPA serves as a vital mechanism for transforming the quality system from reactive to proactive.

Deviations closed without root cause analysis have the potential to lead to recurrence and weaken the quality system. According to Pujari (2026) a modern approach to deviations and CAPA must view deviations as process signals, not merely administrative records to be closed. This means that every deviation needs to be analysed to understand whether the problem stems from personnel, procedures, systems, tools, data, or process design. In this way, CAPA can be directed towards systemic changes that genuinely reduce the risk of recurrence.

CAPA also plays a crucial role in controlling OOS, as test results outside specifications may indicate problems with the analytical method, the sample, the production process, or the raw materials. According to Khan *et al*. (2024), the processes of deviation, OOS, and CAPA are essential components of pharmaceutical quality system documentation to ensure that products meet requirements for identity, purity, safety, and quality. If OOS is not thoroughly investigated, products that do not meet requirements may pass, or decisions to reject a batch may lack a sound basis. Therefore, CAPA must

be implemented with robust documentation, clear investigations, and an evaluation of effectiveness once actions have been taken.

QRM in the Prevention of Quality Failures in Sterile Products

Sterile products carry a high level of quality risk, as process failures can have a direct impact on patient safety. Risks associated with sterile products include microbial contamination, particulate contamination, sterilisation errors, filling errors, container leaks, labelling errors, and improper storage. According to Tharun *et al*. (2026), the application of FMEA to the filling and final handling processes of sterile products helps to identify critical hazards with high RPN values so that they can be controlled immediately. This demonstrates that QRM is crucial in the sterilisation process because even small risks can have major consequences for patients.

In the final stages of sterile product manufacturing, risks arise not only during production but also during sterilisation, inspection, labelling, packaging, transfer, and storage of the finished product. According to Tharun *et al*. (2026), QRM in the final stages of sterile product manufacturing can identify risks such as unsterilised products being handled incorrectly, defective products passing inspection, labelling errors, and uncontrolled storage. These risks must be controlled through clear SOPs, breaking down processes into detailed steps, and risk assessment using FMEA. Thus, QRM helps ensure that sterile products remain safe right through to the final storage stage.

QRM also supports the prevention of contamination through the control of facilities, equipment, personnel and material flows. In sterilisation processes, minor failures such as inadequate cleaning or handling errors can lead to contamination that is difficult to detect directly. According to Alsaidalani & Elmadhoun (2021), the implementation of QRM in the supply chain, warehousing, and dispensing can prevent complaints and delays in subsequent manufacturing processes. Therefore, the control of risks associated with sterile products must begin at an early stage, not just during the sterilisation process.

QRM, QbD and Process Control

Quality by Design (QbD) is closely linked to QRM, as both emphasise the prevention of quality failures from the product and process design stage onwards. QbD helps the industry understand the relationship between raw materials, process parameters, and product quality attributes so that risks can be controlled before routine production begins. According to Galvão *et al*. (2025), QbD is a science- and risk-based approach aimed at reducing batch-to-batch variation and the potential for product recalls. With this approach, quality is not merely tested at the end of the process, but is built in from the very start of development.

QbD utilises the concepts of Critical Quality Attributes (CQA), Critical Process Parameters (CPP), and Design Space to ensure the process remains within the limits that produce consistent quality. According to Khan *et al*. (2024), QbD shifts the quality approach from reactive testing to a proactive method based on science, risk, DoE, FMEA, PAT, and multivariate modelling. The use of these tools helps the industry predict the impact of process changes on product quality. Therefore, QbD and QRM can be used together to prevent deviations from the development stage through to commercial production.

Process control is also a key component in preventing quality failures, as pharmaceutical production processes must operate consistently within predefined parameters. According to Komal *et al*. (2025), the integration of QRM and process control supports the monitoring of CPP and CQA through approaches such as SPC, PAT, and automated control systems. Real-time monitoring enables the industry to detect process changes before producing products that deviate from specifications. Thus, QRM is not only used after a deviation has occurred, but also forms the basis for preventive process monitoring.

QRM in the Supply Chain, Warehousing and Distribution

The supply chain plays a vital role in preventing deviations, as the quality of pharmaceutical products is heavily influenced by the quality of raw materials, packaging materials, suppliers, storage, and distribution. Risks within the supply chain may include delays in the delivery of materials,

suppliers failing to meet standards, changes in material quality during storage, or transport disruptions. According to Fazila *et al*. (2025), supplier qualification is a critical step in ensuring quality, sustainability, and regulatory compliance. Therefore, regular audits, supplier diversification, and the use of digital technology are required as risk mitigation strategies.

In pharmaceutical warehouses, quality risks may arise due to improper storage, incorrect identification of materials, confusion regarding material status, or uncontrolled internal distribution. According to Ilmu *et al*. (2024), a risk assessment using FMEA on the storage and distribution processes of raw materials identified 15 risks ranging from low to very high categories. High and very high-category risks must be controlled immediately to ensure that product quality, safety, and efficacy are maintained. This demonstrates that warehouse activities are not merely logistical operations, but a direct component of the pharmaceutical industry's quality system.

QRM in the supply chain also serves to maintain product availability and prevent production disruptions that could trigger deviations. Raw materials that arrive late or do not meet specifications can lead to changes in production schedules, the use of alternative suppliers that are not yet optimised, or risky process adjustments. According to Alsaidalani & Elmadhoun (2021), QRM at the early stages of manufacturing such as the supply chain, warehouse, and dispensing can prevent complaints and disruptions in subsequent processes. Consequently, deviation prevention must be implemented from the moment materials enter the industrial system.

Digitalisation of QRM and Pharmaceutical Quality Systems

Advances in digitalisation present significant opportunities to strengthen the implementation of QRM within the pharmaceutical industry. Digital systems can facilitate more accurate recording of deviations, tracking of CAPA, trend analysis, integration of quality data, and early risk detection. According to Laxmi *et al*. (2025), digitalisation, artificial intelligence, and blockchain can improve the effectiveness of deviation and CAPA management in API manufacturing. These technologies enable the investigation process to be faster, more transparent, and data-driven.

Digitalisation also helps to reduce the weaknesses of manual systems, such as delays in recording, data loss, document duplication, and misinterpretation of information. According to Pujari (2026), modern deviation and CAPA strategies emphasise the importance of digital connectivity within electronic quality systems to detect weak signals and prevent significant non-conformities. With a digital quality system, data from deviations, audits, complaints, OOS, validation, and CAPA can be analysed in an integrated manner. This helps the industry identify risk patterns that might not be apparent if the data were analysed separately.

In the future, QRM is expected to become increasingly integrated with Pharma 4.0, predictive analytics, digital twins and automated monitoring systems. According to Yang *et al*. (2025), modern QbD has begun to integrate AI, digital twins, continuous manufacturing, and PAT to enhance process resilience and quality control. The use of these technologies can help the industry predict failures before actual deviations occur. Consequently, digitalisation is driving a shift in quality systems from reactive to predictive and preventive approaches.

Challenges in Implementing QRM in the Pharmaceutical Industry

Although QRM offers significant benefits, its implementation still faces various challenges within the pharmaceutical industry. Common challenges include a lack of understanding among staff, subjectivity in risk assessment, data limitations, resistance to change, and suboptimal integration of QRM with quality management systems. According to Komal *et al*. (2025), the implementation of QRM is often hindered by a lack of training, inadequate data, subjective risk assessment, and weak integration with the QMS. These obstacles can lead to inconsistent risk assessment results that are difficult to use as a basis for quality decisions.

Subjectivity in risk assessment is problematic because risk ratings may vary between personnel or departments. Differences in understanding severity, occurrence, and detectability can result in inconsistent risk prioritisation. According to Tharun *et al*. (2026), challenges in QRM include cultural

resistance, a lack of training, and subjectivity in risk assessment. Therefore, the industry needs clear risk scoring criteria, regular training, and the involvement of cross-functional teams.

Another challenge is the persistent view that QRM is carried out solely to meet audit or regulatory requirements. If QRM is regarded merely as a formal document, the risk assessment process will have no tangible impact on preventing deviations. According to Sharma *et al*. (2020), QRM should assist companies and regulators in systematically assessing, controlling, communicating, and reviewing risks. Therefore, the success of QRM requires management commitment, a quality culture, and consistent implementation in operational activities.

Synthesis Analysis

Based on the 25 articles reviewed, it can be seen that QRM serves as the primary approach to preventing quality deviations and failures in the pharmaceutical industry. These articles indicate that risks can arise at every stage, from development, suppliers, warehousing, production, packaging, inspection and distribution, right through to the CAPA system. According to Harsanti & Chaerunisaa (2021), QRM enables the industry to assess, control, communicate, and review risks throughout the product lifecycle. With this approach, quality risks can be controlled at an early stage before they impact the product or patients.

Most articles indicate that FMEA is the most widely used method because it is easy to implement and capable of prioritising risks through the RPN. FMEA is used in various contexts, such as sterile products, packaging, warehousing, the supply chain, GMP inspections, and new product introductions. According to Vyawhare (2025), FMEA in new product introduction helps to identify risks in scale-up, transfer of analytical methods, raw material variations, cleaning validation, packaging integrity, and logistics. This demonstrates that FMEA can be used as a practical tool to prevent deviations as the product moves from the development stage to commercial production.

In addition to FMEA, CAPA, QbD, risk matrices and process control are also key approaches to preventing quality failures. CAPA focuses on resolving root causes, QbD builds quality from the design stage, risk matrices help prioritise issues, whilst process control ensures that process parameters remain within specified limits. According to Qiu *et al*.(2024), the implementation of QRM at PIVAS reduced medication errors, shortened medication preparation times, and increased staff satisfaction. This evidence reinforces the fact that QRM is not merely a theoretical concept, but can deliver measurable operational impacts.

QRM is capable of shifting the approach to quality from reactive to proactive. Without QRM, the industry tends to address deviations after problems have occurred, whereas with QRM, the industry can predict and control risks before problems arise. According to Ismael & Ahmed (2020), the implementation of QRM in the pharmaceutical industry can reduce process risks and improve product quality. Therefore, QRM can be viewed as a crucial foundation in the prevention of deviations, batch failures, OOS, contamination, recalls, and quality non-conformities.

The Implications of QRM for the Pharmaceutical Industry

The implementation of QRM has significant implications for the pharmaceutical industry as it helps companies make quality decisions based on risk levels. Decisions such as batch release, deviation investigations, process validation, supplier changes, audits and complaint handling can be carried out in a more targeted manner when supported by risk assessment. According to Tharun *et al*. (2026), QRM supports risk-based decision-making, improved efficiency, the prevention of quality failures, and patient protection. Thus, QRM helps the industry balance regulatory compliance, operational efficiency, and quality assurance.

From a regulatory perspective, QRM strengthens the industry's preparedness for GMP inspections as every quality decision can be justified with a scientific basis and adequate documentation. Mapped and controlled risks demonstrate that the company understands the processes and has clear mitigation strategies. According to Mashingia *et al*. (2025), GMP inspections and CAPA follow-up play a crucial role in strengthening the regulatory system and quality oversight capacity.

Therefore, QRM helps companies not only meet standards but also demonstrate the maturity of their quality systems.

From a patient safety perspective, QRM plays a role in preventing substandard products from reaching the end user. Risks such as contamination, labelling errors, incorrect dosages, out-of-specification (OOS) products, materials that do not meet specifications, and uncontrolled storage can have a direct impact on patients. According to Elmadhoun *et al*. (2025), risk control at the final stage of sterile products can prevent critical risks such as defective products passing inspection, labelling errors, and inappropriate product storage. Thus, the ultimate goal of QRM is to ensure that every product reaching the patient has consistent quality, safety, and efficacy.

CONCLUSION

The findings of this literature review affirm that Quality Risk Management plays a central and irreplaceable role in the pharmaceutical industry as a proactive strategy for preventing deviations and quality failures throughout the product lifecycle. The implementation of QRM, guided by the ICH Q9 framework and supported by tools such as Failure Mode and Effect Analysis, Corrective and Preventive Action, and Quality by Design, enables manufacturers to systematically identify, evaluate, and control quality risks before they escalate into product defects or regulatory non-compliance. Corrective and Preventive Action, embedded within a risk-based quality system, effectively shifts quality management from reactive problem-solving to proactive risk prevention by addressing the root causes of deviations rather than their immediate symptoms. Quality by Design further reinforces this preventive culture by building quality into the product and process from the earliest stages of development. Robust QRM implementation also strengthens compliance with Good Manufacturing Practice, enhances preparedness for regulatory inspections, and ultimately protects patient safety by ensuring that only products meeting established quality standards reach the end user. Despite ongoing challenges such as subjectivity in risk assessment and the need for a sustained quality culture, the evidence consistently affirms that a well-implemented, science-based Quality Risk Management system is a fundamental commitment to delivering safe, efficacious, and consistently high-quality pharmaceutical products.

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