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Identify Quality Risk Management Fundamentals for Superior Pharmaceutical Industry Experience

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Abstract

Quality Risk Management (QRM) is a fundamental component of pharmaceutical quality systems, playing a critical role in safeguarding patient safety, ensuring regulatory compliance, and supporting consistent product quality. Owing to the highly regulated nature of pharmaceutical manufacturing, systematic and science-based approaches are required to identify, assess, control, and review quality-related risks throughout the product lifecycle. This paper presents a comprehensive review of Quality Risk Management concepts, tools, and applications within the pharmaceutical industry. Emphasis is placed on widely adopted methodologies such as Failure Mode and Effects Analysis (FMEA), Quality by Design (QbD), and Process Analytical Technologies (PAT), and their roles across development, manufacturing, storage, and distribution stages. The reviewed literature is organized according to risk management phases and operational contexts to highlight current practices, benefits, and limitations. The findings indicate that effective implementation of QRM enhances decision-making, improves regulatory confidence, and promotes continuous improvement in pharmaceutical operations. This study provides a structured reference for practitioners and researchers seeking to strengthen risk-based quality management practices within pharmaceutical manufacturing environments.

Keywords

Quality Risk Management; Pharmaceutical Industry; Risk Assessment; Quality Management; Failure Mode and Effects Analysis

1. Introduction

Risk and uncertainty are inherent characteristics of industrial systems and organizational decision-making. Although these terms are frequently used interchangeably, they represent distinct concepts. Uncertainty arises from incomplete knowledge and unpredictable system interactions, whereas risk refers to the likelihood and consequences of identifiable adverse events (Alexandru 2019). Regardless of how carefully industrial processes are designed and controlled, uncertainty cannot be entirely eliminated due to the complexity of internal and external operational environments. Consequently, structured risk management approaches are required to systematically identify, analyze, and mitigate potential risks across industries (Rana and Pitroda 2021).

In the pharmaceutical industry, risk management assumes critical importance because product quality is directly linked to patient safety and public health. Pharmaceutical manufacturing operates under strict regulatory oversight, and failures in quality systems may result in serious clinical, regulatory, and economic consequences. Quality Management encompasses all organized activities that influence product quality throughout its lifecycle, including development, manufacturing, storage, and distribution (Haleem et al. 2015). Within this framework, Quality Risk Management (QRM) provides a systematic and science-based approach for identifying hazards, evaluating risks, and implementing appropriate control strategies to ensure consistent pharmaceutical product quality (Frank et al. 2011).

Regulatory authorities increasingly emphasize the integration of QRM into Good Manufacturing Practices (GMPs) and pharmaceutical quality systems. International guidelines encourage the application of risk-based thinking to improve decision-making, prioritize resources, and minimize potential harm to patients (Nauman and Bano 2014; Alsaidalani and Elmadhoun 2022). QRM is typically structured around key phases, including risk identification, risk analysis, risk evaluation, risk control, risk communication, and risk review, forming a continuous improvement cycle that aligns regulatory compliance with operational effectiveness (Jovanovska-Klincarska et al. 2018).

Several tools and methodologies support the practical implementation of QRM in pharmaceutical operations. Among these, Failure Mode and Effects Analysis (FMEA) is one of the most widely applied techniques for assessing process- and product-related risks (Vartak and Bhagure 2012; Frank et al. 2011). FMEA enables organizations to systematically identify potential failure modes, evaluate their severity and likelihood, and prioritize mitigation actions. In addition, design-oriented approaches such as Quality by Design (QbD) and Process Analytical Technologies (PAT) strengthen QRM by embedding risk awareness into product development and process control activities (Volta e Sousa et al. 2021; Jelsch et al. 2021). These approaches promote proactive quality assurance by emphasizing process understanding rather than reliance on end-product testing (Rajesh Dumpala et al. 2020).

Despite the widespread recognition of QRM importance, its application within pharmaceutical industries remains fragmented. Many existing studies focus on specific tools, isolated lifecycle stages, or particular operational contexts such as sterile manufacturing, supply chain management, or post-approval changes (Alsaidalani and Elmadhoun 2021; Perez et al. 2016; Kumar and Jha 2017). This fragmented implementation limits the ability of organizations to adopt a coherent and integrated perspective on quality risk across the entire pharmaceutical lifecycle. Furthermore, variations in documentation depth, implementation rigor, and tool selection continue to pose challenges for aligning regulatory expectations with operational efficiency (Bhattacharya 2015; Ramnarine et al. 2020).

Accordingly, there is a clear need for a structured synthesis of Quality Risk Management principles, tools, and applications within the pharmaceutical industry. Such synthesis can support more consistent risk-based decision-making and enhance the effectiveness of pharmaceutical quality systems. This paper addresses this need by reviewing Quality Risk Management concepts and practices in pharmaceutical manufacturing, with emphasis on commonly applied methodologies and their role in improving quality performance and patient safety.

1.1 Objectives

The primary objective of this paper is to provide a structured and comprehensive review of Quality Risk Management (QRM) principles and practices within the pharmaceutical industry. Specifically, this study aims to:

1 Clarify fundamental concepts of risk and Quality Risk Management as applied to pharmaceutical manufacturing, with emphasis on their role in protecting patient safety and ensuring regulatory compliance (Alexandru 2019; Frank et al. 2011).

2 Review and categorize commonly applied QRM tools and methodologies, including Failure Mode and Effects Analysis (FMEA), Quality by Design (QbD), and Process Analytical Technologies (PAT), based on their application across different stages of the pharmaceutical product lifecycle (Vartak and Bhagure 2012; Volta e Sousa et al. 2021).
3 Synthesize existing literature on QRM applications in pharmaceutical development, manufacturing, storage, and distribution to highlight current practices, benefits, and implementation challenges (Alsaidalani and Elmadhoun 2021; Kumar and Jha 2017).
4 Identify gaps and limitations in current QRM implementation approaches, particularly related to fragmented application, tool selection, and integration within pharmaceutical quality systems (Bhattacharya 2015; Ramnarine et al. 2020).
5 Provide a structured reference for practitioners and researchers to support more consistent, risk-based decision-making and continuous improvement in pharmaceutical quality management systems.

These objectives guide the organization of the paper and are addressed through a systematic literature review and critical synthesis of existing studies in the pharmaceutical quality risk management domain.

2. Literature Review

2.1 Concept of Risk and Risk Management

Risk management has evolved as a fundamental practice across industrial, financial, and regulatory domains. The concept of risk is commonly associated with the probability and consequences of undesirable events, while uncertainty reflects incomplete knowledge and unpredictability (Alexandru 2019). Effective risk management aims to reduce exposure to adverse outcomes through systematic identification, analysis, and mitigation of risks (Rana and Pitroda 2021). In industrial contexts, risk management supports decision-making related to cost, quality, safety, and operational continuity (Osama et al. 2023).

Several industries characterized as high-reliability organizations, such as aerospace and biosafety laboratories, rely heavily on structured risk governance to balance complex processes with minimal tolerance for failure (Callihan et al. 2021). These principles are directly applicable to pharmaceutical manufacturing, where risk management is not only a business necessity but also a regulatory requirement.

2.2 Quality Risk Management in Pharmaceutical Industry

Quality Risk Management has become an integral component of pharmaceutical quality systems due to the direct relationship between product quality and patient safety. QRM provides a science-based and systematic framework for identifying quality-related hazards, assessing risks, and implementing control measures across the product lifecycle (Frank et al. 2011). Regulatory agencies emphasize QRM as a core element of Good Manufacturing Practices to enhance compliance and ensure consistent product quality (Nauman and Bano 2014).

Several studies highlight that effective QRM enables improved decision-making, increased regulatory confidence, and better allocation of resources toward high-risk areas (Mandhare et al. 2018; Vartak and Bhagure 2012). However, the extent and rigor of QRM implementation often vary depending on organizational maturity, process complexity, and regulatory interpretation (Bhattacharya 2015).

2.3 QRM Tools and Methodologies

A variety of tools and methodologies support the implementation of QRM in pharmaceutical operations. Failure Mode and Effects Analysis (FMEA) is among the most widely used techniques for identifying potential failure modes, evaluating their severity and likelihood, and prioritizing mitigation actions (Frank et al. 2011; Vartak and Bhagure 2012). FMEA has been successfully applied to manufacturing processes, sterile filling operations, and final product handling stages (Alsaidalani and Elmadhoun 2022).

Preventive approaches such as Hazard Analysis and Critical Control Points (HACCP) have also been explored in pharmaceutical contexts, particularly for process control and contamination prevention (Dahiya et al. 2009). More recently, Quality by Design (QbD) has emerged as a comprehensive framework that integrates risk management into product and process development by emphasizing process understanding and critical quality attributes (Rajesh Dumpala et al. 2020; Prajapati et al. 2021).

Process Analytical Technologies (PAT) further enhance QRM by enabling real-time monitoring and control of manufacturing processes. PAT supports continuous improvement and risk-based decision-making by reducing reliance on end-product testing and enhancing process transparency (Volta e Sousa et al. 2021; Jelsch et al. 2021).

2.4 QRM Across the Pharmaceutical Product Lifecycle

The application of QRM extends across all stages of the pharmaceutical product lifecycle, including development, manufacturing, storage, distribution, and post-approval changes. Several studies emphasize the importance of applying QRM during supply chain operations, warehousing, and dispensing to minimize risks associated with storage conditions, handling, and logistics (Alsaidalani and Elmadhoun 2021; Chitmetha et al. 2013).

Temperature excursion management represents a critical risk area, as deviations from specified storage conditions may compromise product quality and patient safety (Kumar and Jha 2017). Similarly, contamination risks in sterile manufacturing and injectable products have been identified as major quality concerns requiring rigorous risk assessment and control strategies (Perez et al. 2016; Sandle 2014).

Post-approval changes introduce additional complexity, as regulatory approval timelines and global compliance requirements may delay improvements intended to enhance quality and reduce risk (Ramnarine et al. 2020). These challenges highlight the necessity of integrating QRM consistently throughout the product lifecycle rather than limiting its application to isolated stages.

2.5 Limitations and Research Gaps in Existing Studies

Despite extensive literature on Quality Risk Management in pharmaceutical industries, several limitations remain evident. Many studies focus on specific tools or individual operational stages without providing an integrated perspective on QRM implementation across the full product lifecycle (Alsaidalani and Elmadhoun 2022; Sharma et al. 2020). In addition, variations in risk assessment rigor, documentation depth, and tool selection contribute to inconsistent application of QRM principles across organizations (Bhattacharya 2015).

Furthermore, while QRM concepts are well established, practical guidance on integrating multiple tools within a unified quality system remains limited. This fragmentation underscores the need for structured synthesis and clearer frameworks to support consistent, risk-based quality decision-making in pharmaceutical manufacturing environments. Figure 1 illustrates the conceptual framework used in this study to synthesize Quality Risk Management principles, tools, and pharmaceutical lifecycle stages (Figure 1).

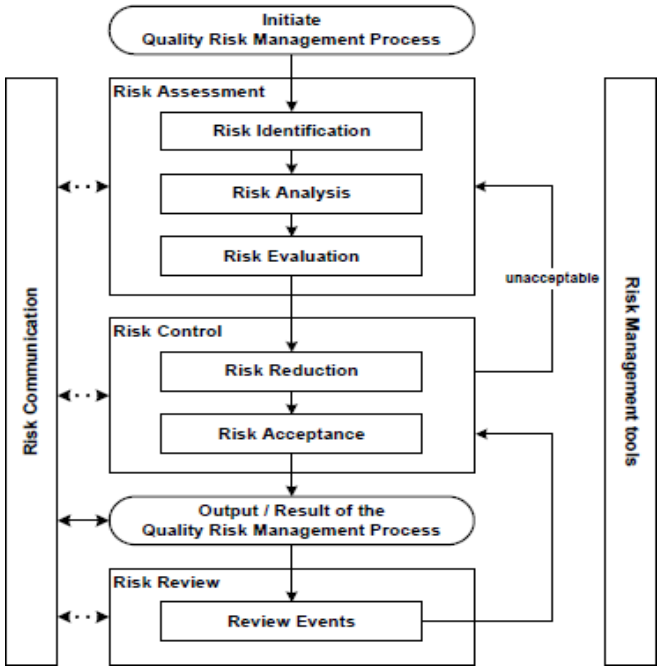

Figure 1. Phases in the QRM process (Jovanovska-Klincarska et al. 2018)

3. Methods

This study adopts a **structured literature review methodology** to examine Quality Risk Management (QRM) principles, tools, and applications within the pharmaceutical industry. The selected approach is appropriate for synthesizing existing knowledge, identifying implementation patterns, and highlighting gaps in current practices across the pharmaceutical product lifecycle.

3.1 Review Scope and Selection Criteria

The scope of the review focuses on Quality Risk Management as applied to pharmaceutical development, manufacturing, storage, distribution, and post-approval activities. Peer-reviewed journal articles, review papers, case studies, and regulatory-oriented studies related to QRM were considered. Only sources directly addressing pharmaceutical quality risk management concepts, tools, or applications were included to ensure relevance and consistency.

The reviewed literature emphasizes established QRM methodologies such as Failure Mode and Effects Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP), Quality by Design (QbD), and Process Analytical Technologies (PAT), as these approaches are widely recognized and frequently referenced in pharmaceutical quality systems (Frank et al. 2011; Dahiya et al. 2009; Volta e Sousa et al. 2021).

3.2 Literature Organization and Classification

To ensure systematic analysis, the selected studies were classified according to three primary dimensions:

1. **Quality Risk Management phase**, including risk identification, risk analysis, risk evaluation, risk control, risk communication, and risk review (Jovanovska-Klincarska et al. 2018).
2. **QRM tools and methodologies**, such as FMEA, HACCP, QbD, and PAT, based on their purpose and application context (Vartak and Bhagure 2012; Rajesh Dumpala et al. 2020).
3. **Pharmaceutical product lifecycle stage**, including development, manufacturing, storage, distribution, and post-approval change management (Alsaidalani and Elmadhoun 2021; Ramnarine et al. 2020).

This classification enabled consistent comparison of QRM practices and facilitated identification of recurring themes, benefits, and limitations reported in the literature.

3.3 Synthesis and Analysis Approach

A qualitative synthesis approach was employed to integrate findings across the reviewed studies. Rather than evaluating individual papers independently, results were analyzed collectively to identify common trends in QRM implementation, frequently applied tools, and areas of convergence and divergence across lifecycle stages.

Emphasis was placed on assessing how QRM tools support regulatory compliance, risk-based decision-making, and continuous improvement in pharmaceutical quality systems (Nauman and Bano 2014; Mandhare et al. 2018). Reported challenges, such as fragmented implementation and variability in documentation rigor, were also examined to identify limitations and research gaps (Bhattacharya 2015; Sharma et al. 2020).

3.4 Conceptual Framework Development

Based on the structured synthesis of the literature, a conceptual framework was developed to integrate QRM phases, tools, and pharmaceutical lifecycle stages. The framework provides a unified view of how QRM methodologies can be systematically applied across pharmaceutical operations to support consistent quality risk management and patient safety objectives. This framework serves as an analytical foundation for organizing the discussion and conclusions presented in subsequent sections.

4. Data Collection

In this study, data collection was conducted through a **systematic gathering of secondary data** in the form of published literature related to Quality Risk Management (QRM) in the pharmaceutical industry. As the paper adopts a structured literature review methodology, no primary experimental, survey-based, or numerical data were collected. Instead, the analysis relies on peer-reviewed journal articles, review papers, and documented case studies that address QRM concepts, tools, and applications within pharmaceutical quality systems.

The collected literature spans a wide range of pharmaceutical product lifecycle stages, including development, manufacturing, storage, distribution, and post-approval activities. Particular attention was given to studies that

explicitly discuss Quality Risk Management phases—risk identification, risk analysis, risk evaluation, risk control, risk communication, and risk review—as these phases form the analytical foundation of this study, as summarized in Table 1 (Jovanovska-Klincarska et al. 2018).

To ensure relevance and consistency, the literature sources were screened based on the following criteria:

- Direct relevance to pharmaceutical quality management or quality risk management;
- Discussion or application of established QRM tools such as Failure Mode and Effects Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP), Quality by Design (QbD), or Process Analytical Technologies (PAT);
- Coverage of risk-related decision-making within regulated pharmaceutical environments;
- Clear linkage between quality risk and patient safety, regulatory compliance, or process performance.

The selected studies were subsequently organized and classified according to three main dimensions. First, publications were categorized based on the Quality Risk Management phase they primarily addressed, enabling comparison of how risks are identified, assessed, controlled, and reviewed across different operational contexts. Second, studies were grouped according to the QRM tools and methodologies applied, allowing evaluation of their practical roles and limitations within pharmaceutical quality systems. Third, the literature was mapped to the pharmaceutical product lifecycle stage at which QRM was implemented, such as development, manufacturing, supply chain operations, or post-approval change management.

This structured classification facilitated qualitative synthesis and cross-comparison of findings across the reviewed literature. Rather than extracting quantitative metrics, the data collection process focused on identifying recurring themes, implementation patterns, reported benefits, and commonly cited challenges associated with QRM practices. The organized dataset served as the foundation for the results and discussion presented in the following section, where insights from the literature are integrated to evaluate the effectiveness and limitations of Quality Risk Management in pharmaceutical industries (Table 1).

Table 1. Risk management processes Definitions (Jovanovska-Klincarska et al. 2018).

The process of risk management	**Process explanation**
Risk identification,	Systematic utilization of information about the problem description or risk question to identify risks
Risk analysis	Risks associated with specified hazards are estimated
Risk evaluation	Comparing the (identified and analyzed) risk to predetermine risk criterion
Risk reduction	Technique for avoiding or mitigating quality risk above an acceptable threshold
Risk acceptance	Choose (assume risk),
Risk communication	Sharing (risk and risk managing data) with decision-makers and further stakeholders
Risk review	Observing the risk management process consequences in light of new risk-related experience and information

5. Results and Discussion

This section presents and discusses the findings derived from the structured synthesis of the reviewed literature on Quality Risk Management (QRM) in the pharmaceutical industry. Given the review-based nature of the study, results are reported qualitatively by integrating evidence across studies to identify dominant practices, recurring challenges, and observed benefits of QRM implementation across pharmaceutical lifecycle stages.

5.1 Qualitative Results

The reviewed literature consistently indicates that QRM is widely recognized as a critical element of pharmaceutical quality systems, particularly due to its direct impact on patient safety and regulatory compliance. Studies report that the adoption of structured QRM approaches improves the ability of organizations to identify high-risk processes, prioritize resources, and implement targeted risk control measures (Frank et al. 2011; Mandhare et al. 2018).

Failure Mode and Effects Analysis (FMEA) emerges as the most frequently applied QRM tool across pharmaceutical manufacturing operations. Its structured scoring mechanism supports systematic identification of potential failure modes and prioritization of mitigation actions (Vartak and Bhagure 2012). Case-based studies demonstrate effective application of FMEA in sterile filling operations, final product handling, and critical manufacturing steps, where risk severity and detectability are particularly significant (Alsaidalani and Elmadhoun 2022).

In addition to FMEA, several studies highlight the increasing adoption of preventive and design-oriented approaches. Quality by Design (QbD) is frequently reported as an effective strategy for embedding risk management into product and process development by emphasizing critical quality attributes and process understanding (Rajesh Dumpala et al. 2020; Prajapati et al. 2021). Similarly, Process Analytical Technologies (PAT) support real-time risk monitoring and control by enhancing process transparency and reducing reliance on end-product testing (Volta e Sousa et al. 2021; Jelsch et al. 2021). Table 2 summarizes the application, benefits, and limitations of major Quality Risk Management tools across pharmaceutical lifecycle stages.

Table 2. Topics of categories and main (Quality , Safety , Efficiency, Multidisciplinary) (Haleem et al., 2015)

Q: Topics/Quality relating to pharmaceutical and chemical Quality Assurance:	**S: Topics/Safety**
(1) Impurities (2) Stability (3) Analytical Validation (4) Biotechnological Products Quality (5) Specifications (6) GMP (7) Development of Pharmaceutical (8) RM (9) Pharmacopoeias	(1) Immuno-toxicology investigations (2) Biotechnological Products (3) Toxicity Testing (4) Genotoxicity investigations (5) Toxicokinetics and Pharmacokinetics (6) Reproductive Toxicology (7) Pharmacology investigations (8) In vivo and in vitro related pre-clinical investigations (9) Joint Efficacy/Safety (Multidisciplinary) (10) Investigations of Carcinogenicity
E: Topics/Efficiency	**M: Topics/Multidisciplinary, they do not fit into any of the preceding categories (topics of Cross-cutting)**
(1) Good Clinical Practice (2) Clinical Investigation Reports (3) Ethnic Factors (4) Dose-Response Investigations (5) Therapeutic Category Clinical Evaluation Guidelines (6) Clinical Trials (7) Clinical Evaluation (8) Clinical Safety	M1: MedDRA (Terminology of Medical) M2: ESTRI (Electronic Regulation Information Transmission Standards) M3: The timing of Pre-Clinical Investigations in Relation to Clinical Trials M4: CTD (The Document of Common Technical) M5: Drug Dictionary Data Standards

5.2 Lifecycle-Based Discussion of QRM Practices

Analysis of the literature across pharmaceutical lifecycle stages reveals uneven application of QRM practices. During development and early manufacturing stages, QRM is more systematically implemented through QbD frameworks and risk-based process design (Rajesh Dumpala et al. 2020). In contrast, downstream stages such as storage, distribution, and dispensing often receive less structured risk attention despite their significant influence on product quality and safety (Chitmetha et al. 2013; Alsaidalani and Elmadhoun 2021).

Temperature excursion management is repeatedly identified as a critical risk area during storage and distribution. Studies report that inadequate monitoring and documentation of temperature deviations may compromise product stability and efficacy, underscoring the need for integrated risk-based control strategies across the supply chain

(Kumar and Jha 2017). Similarly, contamination risks in sterile manufacturing and injectable products remain a major concern, requiring rigorous application of QRM principles to minimize patient exposure to particulate and microbiological hazards (Perez et al. 2016; Sandle 2014).

Post-approval change management represents another area where QRM plays a vital but challenging role. Regulatory complexity and global approval requirements often delay quality improvements intended to reduce risk, highlighting the importance of harmonized, risk-based decision frameworks to support timely implementation of changes (Ramnarine et al. 2020).

5.3 Identified Challenges and Improvement Opportunities

Despite the demonstrated benefits of QRM, several challenges are consistently reported in the literature. One major limitation is the fragmented application of QRM tools, where organizations apply individual methodologies without integrating them into a cohesive quality system (Bhattacharya 2015; Sharma et al. 2020). This fragmentation may reduce the overall effectiveness of risk management efforts and lead to inconsistent decision-making.

Another challenge relates to variability in implementation rigor and documentation depth. Differences in organizational maturity, regulatory interpretation, and resource availability contribute to uneven application of QRM principles across pharmaceutical companies (Nauman and Bano 2014). Furthermore, qualitative scoring methods used in tools such as FMEA may introduce subjectivity if not supported by sufficient process knowledge and cross-functional expertise (Frank et al. 2011).

Improvement opportunities identified in the literature include stronger integration of QRM across lifecycle stages, enhanced use of real-time monitoring technologies, and increased alignment between regulatory expectations and operational risk management practices. Developing unified frameworks that connect QRM phases, tools, and lifecycle stages may help address these challenges and support more consistent quality outcomes.

5.4 Validation Through Literature Consistency

Validation of the findings in this study is achieved through consistency and convergence across multiple independent sources. Similar conclusions regarding the benefits and limitations of QRM are reported across review papers, case studies, and regulatory-oriented publications, strengthening confidence in the synthesized results (Mandhare et al. 2018; Haleem et al. 2015).

The repeated identification of key risk areas—such as sterile manufacturing, temperature excursions, and supply chain operations—across diverse studies further validates the relevance of these findings (Perez et al. 2016; Kumar and Jha 2017; Alsaidalani and Elmadhoun 2021). Moreover, consistent emphasis on structured risk identification, preventive design approaches, and continuous review supports the robustness of QRM as a foundational component of pharmaceutical quality systems.

Overall, the convergence of evidence across the reviewed literature provides qualitative validation for the conclusions drawn in this study and supports the applicability of QRM principles as an effective mechanism for managing quality-related risks in pharmaceutical industries.

6. Conclusion

This paper presented a structured review and synthesis of Quality Risk Management (QRM) principles, tools, and applications within the pharmaceutical industry. The study addressed the growing need for systematic, risk-based approaches to ensure pharmaceutical product quality, regulatory compliance, and patient safety in highly regulated manufacturing environments.

Through a comprehensive review of existing literature, the paper clarified fundamental concepts of risk and QRM and examined widely applied methodologies such as Failure Mode and Effects Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP), Quality by Design (QbD), and Process Analytical Technologies (PAT). The findings indicate that these tools play complementary roles across different stages of the pharmaceutical product lifecycle, from development and manufacturing to storage, distribution, and post-approval change management.

The results highlight that FMEA remains the most commonly applied QRM tool in pharmaceutical manufacturing due to its structured and systematic nature. Preventive and design-oriented approaches, such as QbD and PAT, were found to enhance proactive risk management by embedding quality considerations early in the product lifecycle and enabling real-time process monitoring. However, the review also revealed persistent challenges, including fragmented implementation of QRM tools, variability in documentation rigor, and limited integration across lifecycle stages.

All research objectives outlined in this study were achieved through thematic synthesis and qualitative analysis of the reviewed literature. The paper contributes by organizing dispersed knowledge into a coherent structure, supported by comparative tables and lifecycle-based discussion, thereby providing a practical reference for both researchers and industry practitioners.

Future work may extend this study by developing quantitative frameworks, empirical case studies, or decision-support models that integrate multiple QRM tools within unified pharmaceutical quality systems. Such efforts could further strengthen risk-based decision-making and support continuous improvement in pharmaceutical manufacturing operations.

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