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Evolving Frontiers of Quality Risk Management: Tools, Principles, and Practice in the Pharmaceutical Sector

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Abstract: Quality Risk Management (QRM) is a vital component of pharmaceutical quality systems, ensuring product safety and efficacy throughout the lifecycle. This review highlights the evolution of QRM from its origins in high-risk industries to its current application in the pharmaceutical and biopharmaceutical sectors. Emphasis is placed on regulatory guidance, particularly ICH Q9, which outlines a systematic approach to risk identification, assessment, control, communication, and review. Core principles of QRM include science-based decisions, patient protection, and proportional documentation. Key tools such as HAZOP, HACCP, Ishikawa diagrams, and risk matrices are explored, demonstrating their use in identifying and mitigating potential quality risks. Real-world case studies illustrate the practical application of QRM in areas like facility cleaning and equipment replacement. Overall, QRM supports proactive decision-making, improves regulatory compliance, and enhances product quality, making it an essential practice in pharmaceutical manufacturing and quality assurance.

Keywords: Quality Risk Management (QRM), Pharmaceutical Quality Systems, Risk Assessment, Risk Control, ICH Q9 Guidelines, Pharmaceutical Manufacturing.

1. INTRODUCTION

A fascinating scenario happened 10 years ago in a sector where management decision-making was heavily influenced by quality. A global scramble to find cheaper suppliers began when quality was suddenly pushed to second place after pricing, which ultimately led to widespread outsourcing. Regulatory agencies began to establish risk management standards as the business grew and recognised the need of quality systems for the pharmaceutical and biopharmaceutical industries. Risk management is not a reactive technique; it is a predictive and preventive one.It incorporates globalisation, norms, economics, and the development of quality. the internet, new business strategies, and corporate accountability. In the 1940s, systematic risk management strategies were first created for the defence and nuclear industries. [(1)] Guidelines for the healthcare sector have been released by the International Conference on Harmonisation of Technical Requirement for Registration of Pharmaceutical Products for Human Use, or ICH. "Quality Risk Management" has been explained by ICH in section Q9. The direction The approach and methodology for QRM to add value are explained in ICH Q9.[(2)] The development lifecycle of a medical device product always includes risk management as a crucial component.

It helps those responsible for designing medical devices ensure that their products are reliable, work as intended, and do not endanger patients, operators, or the environment. To put it another way, the primary goal of the risk management cycle is to lower the likelihood that a product defect would arise by putting several preventative measures in place.(3)

A systematic procedure for evaluating, controlling, communicating, and reviewing threats to the quality of a drug (medical) product is called quality risk management, or QRM. Additionally, comprehension of the concepts "quality" and "risk" is essential to the QRM idea. As to ISO/IEC Guide 51, the term "risk" refers to "the combination of the probability of occurrence of harm and the severity of that harm," whereas "quality" refers to "the degree to which a set of inherent properties of a product, system, or process fulfil requirements!".(4)

There are several options, from "do nothing at all" to trying to mitigate the impact of every risk that has been discovered. Like many management issues, this choice will require weighing the costs and probabilities of insurance that takes risk into account. According to the models, three actions are required to control these optional risks:(5)

(1) risk recognition;

(2) risk prioritization; and

(3) risk management.

Although it can be helpful, effective quality risk management cannot replace appropriate industry-regulator communications or absolve the industry of its need to comply with regulatorystandards. The ultimate purpose of any pharmaceutical company is to provide patients with safe and effective medications.Quality risk management provides a strong foundation for accomplishing this goal by methodically addressing possible risks to the calibre of the final output. By recognising hazards at the outset of Pharmaceutical businesses can reduce the possibility of problems during manufacturing, testing, and distribution by taking proactive steps to manage these risks during the development phase.(6)

SCOPE

Guidelines and illustrations of quality risk management instruments pertaining to many facets of pharmaceutical quality are offered in this regard. These viewpoints address the creation, manufacturing, distribution, analysis, and accommodation/survey forms over the course of the lifecycle of pharmaceuticals, drug products, organic products, and biotechnology products (including the material tagging and bundling in pharmaceutical, natural, and biotechnological products, as well as the use of excipients, solvents, and crude materials).(7)

Principe Of Quality Risk Management (8,9)

There are four main QRM principles:

1. The assessment of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient.

2. QRM should be dynamic, iterative and responsive to change.

3. The level of effort, formality and documentation of the QRM process should be commensurate with the level of risk.

4. The capability for continual development and enhancement should be embedded in the QRM process.

GENERAL QUALITY RISK ADMINISTATION PROCESS

The methodical process of assessing, managing, communicating, and reviewing threats to the drug product's quality throughout its lifecycle is known as quality risk management. The combination of the likelihood that harm may occur and the seriousness of that harm is known as risk.(10)

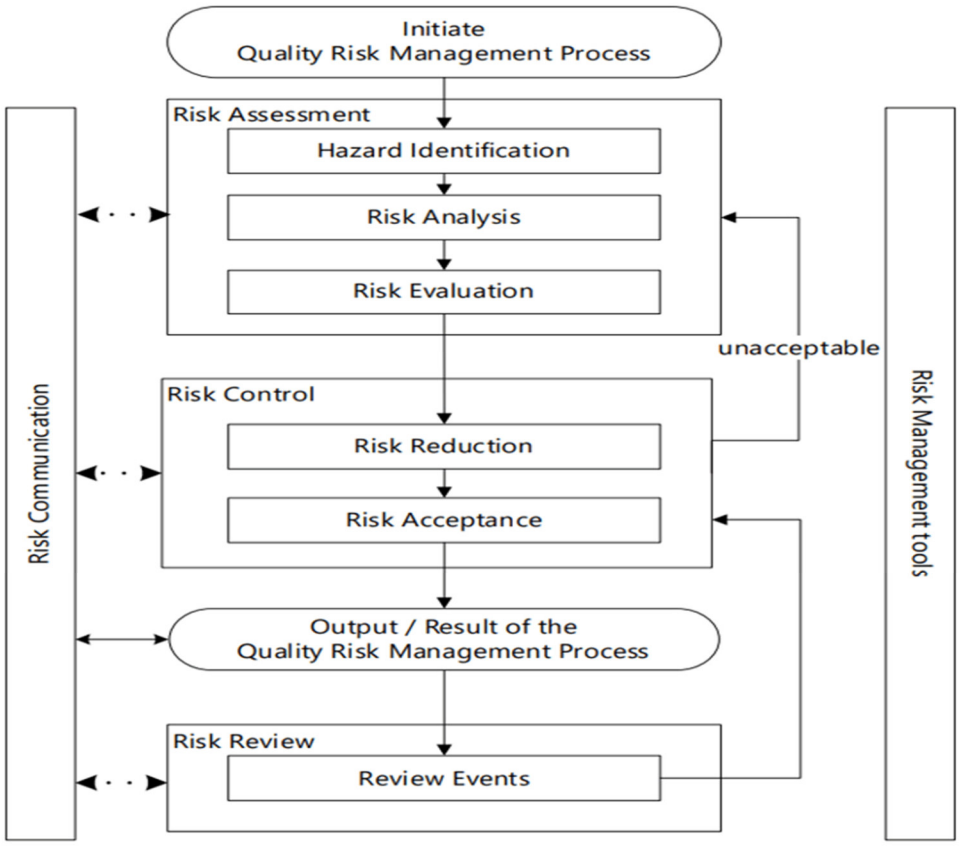


figure 1-Layout of Quality Risk Management Process [10]

1. Initiating A Qrm Process:(11)

QRM operations should be carried out using systematic processes designed to support, coordinate, and improve risk-based, science-based decision-making. Potential steps that could be used to initiate and plan a QRM process include the following:

- Define the problem and/or risk question, including pertinent assumptions identifying the potential for risk;
- Assemble background information and/ or data on the potential hazard, harm or human health impact relevant to the risk assessment;
- Identify a leader and necessary resources;
- Specify a timeline, deliverables and appropriate level of decision making for the risk management process.

2. Risk Assessment (8,9)

The methodical identification of possible risks, followed by an evaluation of the likelihood that those risks would materialise and the seriousness of their possible effects, is known as risk

assessment. It involves three key steps: spotting the risks, understanding and measuring their likelihood and impact, and assessing how significant they are.

Reflecting on three essential questions typically provides valuable insight.

1. What might go wrong?

2. What is the possibility that it will go wrong?

3. What are the consequences?

a) To identify hazards associated with a particular risk, a systematic process of collecting and analysing all relevant data is known as risk identification. Stakeholder input, professional opinions, theoretical studies, and historical documents may all be included in this data. Answering the question, "What could possibly go wrong?" and outlining the possible results are the goals. This phase lays the foundation for the quality risk management processes that follow.

b) **Risk analysis** entails evaluating the severity of hazards you've identified. It can be either qualitative using judgment or quantitative using numerical data to link how likely an event is to occur with how serious its consequences could be. Some methodologies also factor in detectability, meaning how easily the risk can be discovered, to better gauge the overall threat level.

c) **Risk evaluation** Comparing the hazards that have been discovered and examined with predetermined risk criteria. This step takes into account how strong the evidence is in addressing the three key questions of the risk assessment process.

Different Steps Involved I n the Risk Assessment Are: (12,13)

- **Collect & organize the information.**

✓ Gathering relevant information, reviewing appropriate references & identifying assumptions.

✓ Define the limits of the QRM exercise.

- **Formulate the Risk Question:**

✓ With this, the Quality Risk Management (QRM) process officially begins. It gives a high-level overview of the problem and the goals of the QRM exercise. Identifying risk factors, describing the issue's scope, and admitting any related restrictions or constraints are all included.

- **Choose Tool different tools include-**

✓ Utilize fundamental tools such as flowcharts, check sheets, process mapping, and cause-and-effect diagrams to systematically organize and analyze information.

✓ Failure Mode Effects Analysis and Failure Mode Effects and Criticality Analysis.

✓ Fault Tree Analysis.

✓ Hazard Analysis and Critical Control Points. Hazard & Operability Analysis. Preliminary Hazard Analysis.

✓ Risk Ranking & Filtering. Supporting statistical tools.

- **Identify Risks Factors and Related Hazards**

✓ Any possible source of danger to patients is referred to as a hazard. Following identification, these risks can be methodically divided into five main categories: Specimen,

Operator, Environment, System, and Reagents. This classification makes it easier to identify the controls that are required to successfully reduce related risks.

- **Define the Risk Components &Scales**

RISK = PRIORITY * DETECTABILITY * SEVERITY

Where,

Severity- Criticality of the product.

Priority -Complexity of the site (multi-product).

Detection- Audit history.

- **Evaluate the risk for each hazard.**

✓ This step is where you determine the frequency of failures.

- **Determine acceptability of risks [6,7]**

✓ After assigning risks, the next stage is to assess the likelihood and seriousness of possible harm to decide if the risks are acceptable.

Risk evaluation score

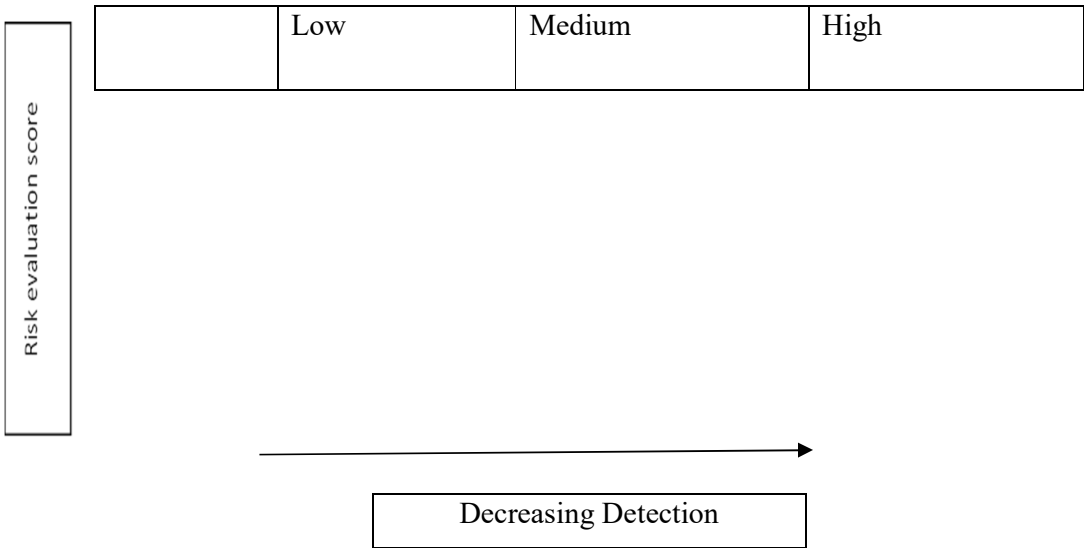
Increasing probability

High	Medium	High	High
Medium	Low	Medium	High
Low	Low	Low	Medium
	Low	Medium	High

Increasing severity

Final risk evaluation score

High	Medium	High	High
Medium	Low	Medium	High
Low	Low	Low	Medium
Low	Low	Low	Medium



- **Determine Action Threshold**

A threshold represents a defined point or value that determines the initiation of an action; if a measurement exceeds this level, action is taken; if it falls below, no action is necessary.

- **Apply the tool**

Evaluate each identified risk by assessing how severe its impact could be and how likely it is to occur. Use scales to assign values for severity, probability, and detectability, and then calculate an overall risk score.

Determine the necessary actions based on the established threshold levels.

3. Risk Control [14]

Making decisions with the intention of lowering or accepting risks is known as risk control. The main goal is to reduce risks to a manageable level while making sure that the amount of work put into risk control is commensurate with the risk's importance. To decide on the ideal degree of risk control, decision-makers frequently use a variety of techniques, such as benefit-cost analysis.

Risk control might focus on the following questions:

• Is the risk above an acceptable level?

• What can be done to reduce or eliminate risks?

• What is the appropriate balance among benefits, risks and resources?

• Are new risks introduced as a result of the identified risks being controlled?

(A) Risk Reduction

Processes for mitigating or avoiding quality risk when it above a predetermined (acceptable) threshold are the focus of risk reduction (see Fig. 1).Risk reduction involves actions to lessen both the likelihood and severity of potential harm**.** This may include improving hazard detection and implementing quality control measures. However, these actions can introduce new risks or increase existing ones. Therefore, it's important to reassess the risks after implementing changes to ensure they remain acceptable.

(B) Risk Acceptance

This choice may be passive, in which case the residual hazards are not specifically mentioned, or formal, in which case the remaining dangers are well-defined and recorded. In certain situations, even with strong, high-quality risk management procedures, there are a number of variables that should be considered individually. It might not be feasible to completely remove every risk. It is generally accepted that suitable tactics have been used in these situations to bring the risk down to a manageable level.

4. Risk Review

Risk review involves regularly reassessing the outcomes of the risk management process to incorporate new knowledge and experiences. Once initiated, the quality risk management process should continue to be applied to events that might impact the original decisions, whether these events are planned (such as results from annual product reviews, inspections, audits, or change controls) or unplanned (such as findings from failure investigations or recalls). This ongoing evaluation ensures that the risk management process remains relevant and effective in addressing emerging risks and changes in circumstances.

5. Risk Communication

Risk communication refers to the exchange of information regarding risks and their management between decision-makers and other relevant parties. The findings and outcomes of the quality risk management process should be effectively communicated and recorded. This information may include details about the presence, type, likelihood, seriousness, acceptability, control measures, treatment, detectability, or other factors related to quality risks(8).

6. Risk Management Tools :(15)

The Hazop (Hazard And Operability Studies)

The HAZOP (Hazard and Operability) method is widely regarded as the preferred approach for detecting design flaws and is extensively used in the manufacturing sector globally. However, a major limitation of this method is its inability to effectively analyze more complex scenarios, particularly those involving multiple independent events occurring simultaneously.

Haccp (Hazard Analysis And Critical Control Points)

HACCP (Hazard Analysis and Critical Control Points) focuses on identifying critical control points during the risk assessment process. These critical points are essential for evaluating a product or service, as they highlight possible deviations from acceptable standards. This information guides necessary actions to ensure the final product or service meets the organization's planned specifications, thereby maintaining consistency and quality.

The Brainstorming Method

Brainstorming is mainly a qualitative technique used to creatively explore potential problems and solutions within a process. In risk analysis, it helps identify possible threats. However, to effectively manage these risks, it is important to complement brainstorming with other methods that provide quantitative data. These methods offer precise numerical values to better assess the significance of risks, allowing for more accurate project evaluation and prioritization of risks based on their importance in the process.

Risk Mapping –

Risk mapping involves identifying risks, measuring their likelihood and potential impact, and assigning labels that are used in visual tools like matrices and scoring scales. Risk scores are calculated by multiplying the probability of a hazard occurring by its effect on the process. These scores are then labeled and placed into a matrix, which organizes risks based on their

severity and probability. This matrix helps categorize risks as dangerous, critical, minimal, or routine, aiding in risk prioritization

The Ishikawa (Fish-Bone Diagram) Cause-And-Effect

The ishikawa cause-and-effect diagram is used to analyze the factors that lead to a particular problem through evaluating items from the problem cause groups. Based on the information obtained, the probable causes that lead to the problem can be identified. The diagram is named after the creator Kaor Ishikawa, for whom Pipunić and Grubišić (2014) state that he "advocated the thesis that quality improvement is a continuous process that can always be further improved." It is also called a fish bone diagram because of its characteristic appearance. According to Čelar et al. (2014) Ishikawa "in his considerations found that there are 6 major groups of causes in the occurrence of errors and called them 6M: machine, method, material, man (manpower, mind power), measurements and the environment (Milieu / Mother Nature)."

Case Studies Related To Quality Risk Management(16)

Case Study No: RMWG-02

Title: Non-Sterile Facility Cleaning Requirements

System: Quality Risk Tool: Decision Tree and Risk Matrix

Brief Description: Risk assessment used to define minimum cleaning requirements (excludes aseptic and potent compounds).

Link:https://pqri.org/wp-content/uploads/2016/03/Case_Study_RMWG-02_-_Non-Sterile_Facility_Cleaning_rev_1.pdf

Case Study No: RMWG-03

Title: Functional Equivalence for Equipment Replacements

System: Facilities & Engineering

Risk Tool: FTA

Brief Description: Risk-based approach used to define a functional equivalence assessment process.].

Link:https://pqri.org/wp-content/uploads/2016/03/Case_Study_RMWG-03_-_Functional_Equivalence_for_Equipment_Replacements_rev_1.pdf

Applications Of Quality Risk Management (Qrm)(17)

Quality Risk Management (QRM) is an essential process across various sectors to identify, assess, and mitigate risks to ensure product quality, regulatory compliance, and operational excellence. Below are some key applications:

1. Pharmaceutical Industry:

- In the pharmaceutical sector, QRM is employed to manage risks related to product safety, efficacy, and regulatory compliance. Risk management processes such as hazard analysis, failure mode effects analysis (FMEA), and risk assessment are used to ensure the safety of drugs and medical devices.
- QRM helps in prioritizing risks based on their impact and likelihood, guiding decisions around the design, testing, production, and distribution of pharmaceutical products.

2. Food And Beverage Industry:

- QRM is used to identify risks related to food safety, such as contamination, shelf-life, and regulatory compliance. Hazard Analysis Critical Control Points (HACCP) is a key framework in which QRM is applied, helping manufacturers ensure that food products are safe and meet quality standards.
- This application also includes managing risks in packaging and logistics to avoid contamination during storage and transportation.

3. Aerospace And Automotive Industries:

- Both aerospace and automotive sectors use QRM to identify risks associated with product performance, safety, and regulatory requirements. Risk management tools like FMEA and Fault Tree Analysis (FTA) help in predicting failure modes in critical systems (e.g., aircraft engines or car braking systems).
- These sectors apply QRM to enhance reliability and safety, ensuring compliance with rigorous industry standards.

4. Healthcare Industry:

- Healthcare institutions use QRM to assess and mitigate risks in patient care, including diagnostic errors, treatment protocols, and patient safety. The goal is to reduce adverse events, improve the accuracy of medical interventions, and enhance patient satisfaction.
- Risk management models also assist in ensuring compliance with health regulations and managing potential risks related to medical devices.

5. Software Development And It Systems:

- In software engineering, QRM is applied to identify and address risks related to system failures, cybersecurity breaches, and data integrity issues. Risk management practices ensure that software systems meet both functional and security requirements.
- Techniques such as risk-based testing and threat modeling are part of the QRM approach in IT systems.

6. Supply Chain Management:

- QRM is critical for managing risks in supply chains, including disruptions, delivery delays, and fluctuations in demand. Risk management frameworks help businesses design resilient supply chains by identifying potential threats and devising contingency plans.
- In global supply chains, QRM ensures that companies comply with international standards and regulations to avoid penalties and supply chain bottlenecks.

7. Financial Services:

- In banking and insurance, QRM is applied to identify and mitigate risks related to fraud, financial loss, regulatory changes, and market volatility. Risk assessment models help financial institutions forecast potential risks and take preventive actions to ensure financial stability and compliance.
- These systems also aid in managing credit, operational, and liquidity risks in the face of changing market conditions.

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