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Review Article

Quality Risk Management in Pharmaceutical Industry

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The purpose of this article is to present Quality Risk Management (QRM) concepts and tool examples. It is applicable to various facets of pharmaceutical quality. Throughout the drug's lifecycle (Staring material, intermediate goods and finished product), these elements include development, production, distribution, inspection, and submission of review processes. "The total and ongoing process of reducing risks to a product's quality overall its lifecycle in order to maximize its benefits and balance the risk is known as quality risk management". The process involves evaluating, controlling, communicating, and reviewing potential hazards to the quality of a pharmaceutical product. The QRM process should be formal, effort-based, feasible and documented to match the level of risk. QRM principles are widely used in various businesses, including pharmaceutical industries, insurance, public health, pharmacovigilance and by regulatory authorities. Risk assessment involves studying, identifying, and evaluating risks and its impacts. QRM plans should be revisited adhering to follow-up. The QRM implementation provides documented, clear, and reproducible procedures to assess and manage sthe probability, severity, and detectability of hazards. QRM solutions help the pharmaceutical business and regulators assess, manage, communicate, and review risks. Implementing QRM effectively can improve decision-making and give regulators with assurance about a company's risk management capabilities.

Keywords: Patient safety, Product quality

INTRODUCTION

Quality Risk Management (QRM) has been a mandated regulatory requirement for healthcare businesses for the past few years. QRM is a comprehensive and ongoing process that aims to balance risk and maximize benefits by reducing hazards to product quality over the course of its lifecycle. It is a precise procedure for assessing, managing, communicating, and reviewing risks to the pharmaceutical product's quality. It promotes practical and science-based judgments when included into quality systems, such as auditing, inspection, documentation, training, validation, and quality defects investigation. The concepts of quality risk management are successfully applied in a variety of fields, such as public health, pharmacovigilance, business, insurance, and work-related safety, as well as by organizations that oversee these sectors. Although there are a few instances of effective risk management in the pharmaceutical sector, they are few and do not fully capture the potential benefits of risk management. Regarding medications, even though there are many entities involved, such as patients, doctors, the government, and business, in the patient's safety by controlling quality risk and patient safety should be given top priority. There is always certain risk involved in the production and use of a pharmaceutical product, including its constituent parts. By identifying and controlling possible quality concerns during development and production, an efficient QRM method can further assured the patient receives a high-quality drug product. When a quality issue occurs, using QRM can help with decision-making. Effective QRM implementation can facilitate better and well versed decisions which can provide regulators with greater assurance of a company's ability to deal with possible risks.[1,3]

Quality Risk Management Principles [1,2]

The assessment of quality risk should be based on scientific knowledge and ultimately linked to patient safety, according to the first of QRM's four key ideas.

1. Risk Assessment

2. QRM should be dynamic, flexible, and iterative.
3. The effort, formality, and documentation of the QRM process should all match the level of risk.
4. The ability for continuous development and improvement should be incorporated into the QRM method.

Starting a Process for Quality Risk Management

Systematic procedures intended to plan, support, and enhance risk-based, scientific decision-making should be a part of quality risk management. The following actions might be taken to initiate, manage and organize a quality risk management process: [1]

Describe the issue and/or risk query, taking into account any pertinent presumptions. Determine the risk possibility.

Compile background data and/or information on the probable risk, injury, or effect on human health that is relevant to the risk assessment.

Indicate the risk management process's schedule and suitable decision-making level.

Risk Assessment: Risk identification, analysis, and appraisal of the risks connected to exposure to certain hazards comprise risk assessment. Identification, analysis, and appraisal of risks are all included. [5] Three basic inquiries are frequently beneficial

1. What might go wrong?
2. How likely is it that anything will go wrong?
3. What are the repercussions?

The systematic use of data to pinpoint dangers associated with a risk is known as risk identification. Chronological data, theoretical analysis, and stakeholder concerns are examples of information. The "What might go wrong?" issue is addressed by risk identification, which also identifies potential outcomes. This serves as the foundation for subsequent phases in the system of quality risk management. The evaluation of the risk connected to the hazards that have been discovered is known as risk analysis. The evaluation of the risk connected to the hazards that have been discovered is known as risk analysis which may cause irreversible damge . It is the qualitative or quantitative method of establishing a connection between the severity of damages and their probability of occurring. Certain risk management techniques also take delectability—the capacity to identify harm—into account when estimating risk. Risk evaluation contrasts the risk that has been recognized and examined with the specified risk criteria. Risk assessments take into account the quality of the evidence supporting each of the three main questions.

The several steps that make up the risk assessment are [5,6].

Gather and arrange the data. collecting pertinent data, examining pertinent references, and recognizing presumptions. The information may be categorized using tools. Specify the QRM exercise's boundaries.

2. Create the Risk Question:

This is the first step in the QRM exercise and a high-level statement that describes the problem and the reason for doing it. It includes risk factors, the issue's scope, and any associated limitations or restrictions**.**

3. Select a tool:

Among the various tools are flowcharts, check sheets, and other basic risk management facilitation techniques.

The analysis of failure mode effects and criticality.

Analyzing fault trees.

Analysis of Hazards and Important Control Points.

Analyzing hazards and operability.

Initial Hazard Assessment.

Ranking and Filtering of Risk.

Auxiliary statistical instruments.

4. Determine the Relevant Hazards and Risk Fators

A failure that has the potential to injure the patient is a hazard. Operator, Environment, System, Reagents, or Specimen are the five categories into which the hazards might be divided after they have been identified. These classifications will facilitate the subsequent identification of the kinds of measures required to lower undesirable risk.

5. Describe the Risk Elements and Levels [4] Priority detectability severity equals risk. The product's criticality and severity. Priority: The site's complexity (multi-product). Detection: History audit.

6. Assess each hazard's level of risk. You determine how frequently a failure will occur in this step. 7. Assess the risks' acceptability [6, 7].After assigning the

risks, the following stage is to assess their likelihood and seriousness in order to decide if they are acceptable or required mnage.

8. **Establish the Threshold for Action** An action will occur at a certain level or value, and it won't below that. 9. Use the instrument create a risk score by analyzing the specific dangers and quantifying them using the severity, probability, and detection scales. Determine the necessary steps based on the action threshold.

General Quality Risk Management Process

Quality Risk Management is a systematic process for evaluation, control, communication and review of risks to the quality of the drug product across the product lifecycle. Risk can be defined as the combination of the probability of occurrence of harm and the severity of that harm.[4,5]

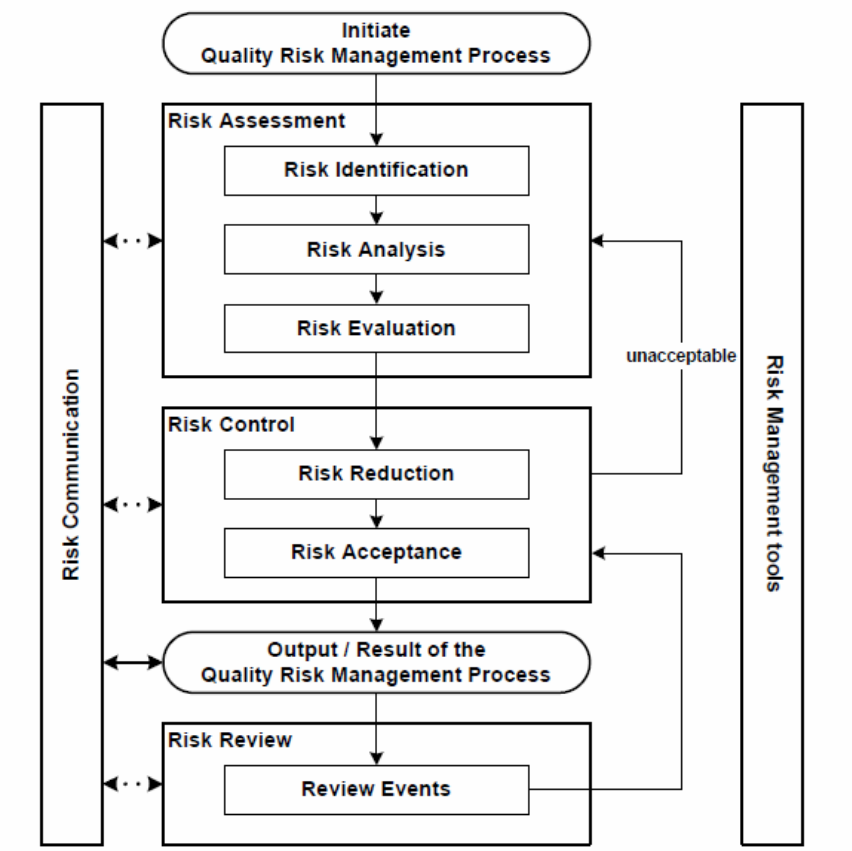


Figure 1: Overview of a Typical Quality Risk Management Process [1]

Risk management: Making decisions to lower and/or accept risks is part of risk control. Reducing the risk to a manageable level is the goal of risk control. The effort put into risk control should be commensurate with the risk's importance. [12,13]

The following inquiries could be the main focus of risk control:

- Is the risk higher than what is reasonable?
- What steps could be taken to lessen or eliminate risks?
- What is the proper ratio of resources, risks, and benefits?
- Does the control of identified hazards result in the introduction of additional risks?

Risk reduction focuses on procedures for minimizing or avoiding quality risk when it surpasses a predetermined threshold. One way to reduce risk is to take steps to lessen the likelihood and severity of injury. The system may become more vulnerable to new risks or other risks may become more significant as a result of the application of risk mitigation strategies. In order to detect and assess any potential change in risk following the implementation of a risk reduction procedure, it may be appropriate to revisit the risk assessment.

The choice to accept risk is known as risk acceptance. Even the best risk management techniques may not completely remove risk for some kinds of injuries. For this reason, it may be said that a suitable quality risk management approach has been used and that quality risk has been lowered to a predetermined (acceptable) level. Numerous factors will determine this (defined) acceptable amount, which should be determined case-by-case. The outcomes of the risk management procedure should be examined to consider fresh insights and expertise. Events that could affect the initial quality risk management decision should continue to be handled through the use of the quality risk management process once it has been started. Rethinking judgments about risk acceptance may be part of the risk review process.

The exchange of information between decision-makers and others regarding risk and risk management is known as risk communication. It is important to properly convey and document the product or outcome of the quality risk management process. Information about the existence, type, form, likelihood, severity, acceptability, control, treatment, detectability, and other elements of quality hazards may be included.

The method outlined can be applied to [14]:

Examine goods and procedures in-depth to make sure the best scientific justification is in place to increase the likelihood of success.

Determine critical knowledge gaps and the procedures that must be comprehended in order to correctly evaluate risks. Establish a communication channel that will work best for all stakeholders participating in the risk management plan. Facilitate the transfer of process knowledge and product development history to enhance general company understanding and facilitate product evolution. Permit the pharmaceutical sector to follow external regulatory guidance's description of a risk-based strategy to development. The outputs of risk management may serve as reference materials for discussions of control strategies and product development in regulatory filings.

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