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Original Article

Quality Risk Management in Pharmaceutical Industry: A Review

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ABSTRACT

This piece intends to outline the foundational principles and practical examples of Quality Risk Management (QRM) tools applicable across various facets of pharmaceutical quality assurance. These facets encompass development, production, distribution, inspection, and the submission of review processes throughout the drug substance, product, and biological product lifecycles. Quality Risk Management represents a comprehensive and ongoing endeavour to reduce risks to product quality throughout its lifecycle, aiming to maximize its benefits while maintaining a risk benefit balance. It is a structured approach for assessing, managing, communicating, and reviewing risks to the product's quality. The core QRM process should encompass the required effort, formalities, and documentation that align with the risk level. The principles of Quality Risk Management are effectively applied in numerous sectors, including business, government, insurance, workplace safety, public health, pharmacovigilance, and regulatory oversight. The risk assessment process involves analysing, identifying, and evaluating risks, followed by the review of QRM strategies.

Keywords: Quality management system, Total quality management, WHO, ICH, quality by design

INTRODUCTION

life cycle, quality risk management (QRM) is a Quality Risk Management comprehensive and ongoing (QRM) has been a mandated process that aims to minimize regulatory obligation for risks to the product's quality while healthcare businesses for the past balancing the associated hazards. few years (1). Throughout a product's It follows a methodical procedure for identifying, managing, sharing, and reviewing risks to the pharmaceutical product's quality. It supports science based and practical decisions when integrated into quality systems, examples of quality systems include Validation, Quality Defects- Investigation, Auditing, Inspection, Documentation, Training etc.(1) Quality Risk Management principles are effectively utilized in many areas including business, insurance, work related safety, public health, pharmacovigilance, and by agencies regulating these industries (2). Even though there are some examples of the use of quality risk management in the pharmaceutical industry, today they are limited and do not represent the full contributions that risk management has to offer. In relation to pharmaceuticals, though there are a variety of stakeholders, including medical practitioners and patients as well as government and industry, the safety of the patient by managing the risk to quality should be considered prime importance. The manufacturing and use of a drug product, including its components, necessarily involve some degree of risk. Use of QRM can ameliorate the decision making If quality problem arises.(3)

2.Defining Risk:

Preliminary working definitions from ICH EWG on QRM Q9:

Risk :- Combination of the probability of occurrence of Harm and the severity of that harm. ISO 14971.

Harm :-Damage to health, including the damage that can occur from loss of product efficacy, safety, Quality or availability.

Quality:-Degree to which a set of inherent characteristics of a product, system or process fulfils requirements.

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Requirements :- Needs or expectations that is stated, generally implied or obligatory by the patients or their Surrogates (e.g. health care professionals, regulators and legislators).

Combining key terms :- Risk to quality is the probability/severity that drug will fail to meet the needs/expectations of the patients and their surrogates.(4)

3. Quality Risk Management:

English Quality risk management has become an important issue in quality management in many manufacturing functions. It is a project management tool and a key element of quality by design. ICH Q9 introduced quality risk management (QRM) guidelines which were adopted in November 2005 (Vesper and O Donnell, 2016). However, Donnell and Greene (2007) developed a practical QRM approach to facilitate compliance with EU Good Manufacturing Practice (GMP) requirements and the ICH Q9 guideline. The researcher called for further efforts to promote the continued development of environmental QRM (GMP) methods and approaches to minimize and manage risks posed by medicines to patients. In 2008, Frank et al. (4) (2011) demonstrates the efforts of the Risk Management Working Group in assembling industry case studies aimed at improving the understanding and application of ICH Q9, including n of eight industry representatives and the US FDA. They demonstrate the need to select the appropriate risk methodology for the target need, taking into account the complexity and risks associated with the specific issue and the importance of predetermining the potential risk classification so as not to be influenced by the outcome of the assessment when determining the appropriate response.2013, practical means for analyzing quality risks. machine had been defined through Lotllikar MV who supplied guidance long side the manner to acquire powerful nice control and compliance thru QRM, the paper concluded that when making use of chance control to pharmaceutical enterprise it will lessen the quantity of threats or reduce their effect the constant use of the tools/techniques and periodic review, the output of the chance control helps the corporation to meet the described dreams closer to safety of public health (Lotllikar, 2013) (4). As Muhammad and Rehana (2014) proved that QRM improves chance consciousness and hastens detection of potential problems the usage of nice statistics to control product nice, production tactics and compliance inside a chance primarily based totally Quality Management System, the very last item will make certain the excessive nice of the drug product to the patient .According to Haleem et al. (2015), chance Management is a vital nice subjects won the unique difficulty in chemical and pharmaceutical nice assurance, they invited each managers on the pharmaceutical enterprise and literature to recognition at the adoption of practices like lean production, Six Sigma and overall nice control into the pharmaceutical enterprise to reduce the opportunity of QRM. Kumar and Jha (2018) admitted that there are instances of unresolved client court cases and batch disasters originated due to inadequacies all through distribution of pharmaceutical Products, they added a version to lessen the product rejection the usage of Risk.

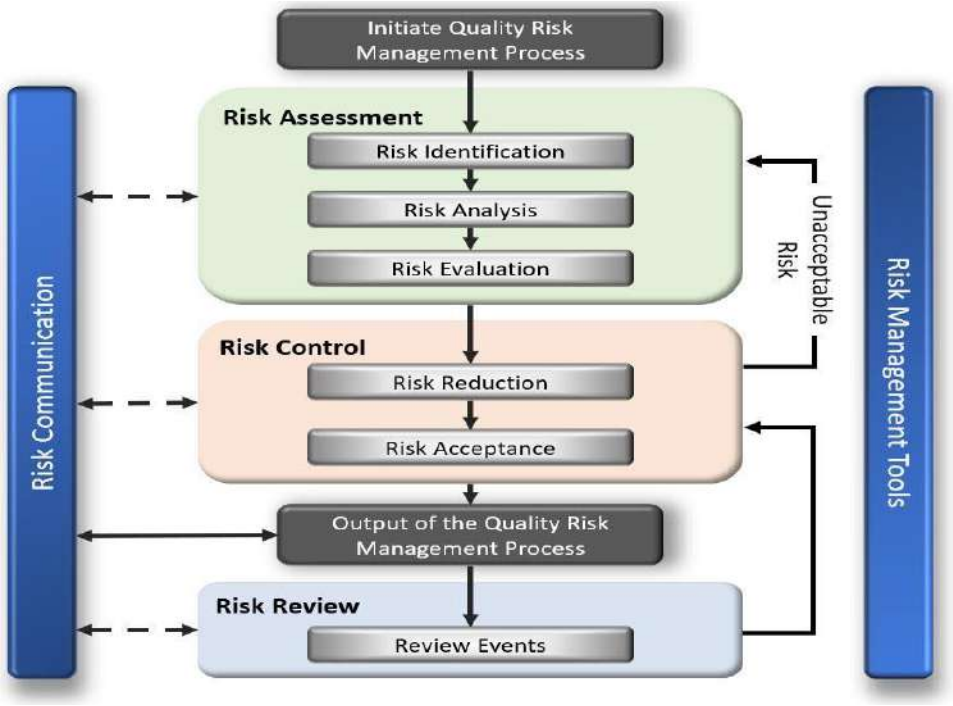

Figure 1: Quality Risk Management

Priority Number (RPN), then they know as for a mechanism for nice chance control all through pharmaceutical distribution to perform client pleasure without apprehension of drug regulatory movements due to nice chance (4). According to those preceding views, which centered at the software of nice chance control within side the pharmaceutical enterprise, so this paper we strive to recognition at the ranges of making use of nice chance control within side the maximum unsafe Industries.

4. Principle Of Quality Risk Management

Two primary principles of quality risk management are;

- The assessment of the risk to quality must rely on scientific understanding and ultimately contribute to safeguarding the patient; an
- The intensity, formal nature, and record-keeping requirements of the quality risk management procedure should match the risk's severity. (5)

5. General Quality Risk Management Process

Drug product quality risk management involves a structured approach to evaluating, managing, communicating, and examining risks related to the quality of medicinal products throughout their entire life cycle. The diagram (Figure 1) presents a framework for quality risk management, although alternative frameworks may also be employed. (6) The decision points are not depicted in the diagram provided because decisions can happen at any stage of the process. These decisions could involve going back to the earlier step to gather more information, modifying the risk models, or concluding the risk management process if the information supports such a move. It's important to note that "unacceptable" in the flowchart doesn't just mean noncompliance with legal, legislative, or regulatory standards; it also encompasses the necessity to reconsider the risk evaluation process. (7)

4.1 Responsibilities

Activities related to managing quality risks are often carried out by teams made up of people from different fields. However, this isn't a guarantee. When these teams are created, they must have members who are specialists in the relevant fields (such as quality control, business growth, engineering, regulatory matters, manufacturing processes, sales and marketing, law, data analysis, and healthcare). It's also important to have people who understand the process of managing quality risks.

Decision makers should

- assert accountability for organizing quality risk management throughout different roles and sections within their company; and

- guarantee that a process for managing quality risks is established, implemented, and evaluated, ensuring sufficient resources are in place.(7)

4.2 Initiating a Quality Risk Management Process

Effective management of risks should encompass organized methods aimed at aligning, supporting, and enhancing decisions based on scientific principles concerning risk. The steps involved in starting and organizing a risk management process could include:

Clearly outline the issue or risk question, including relevant assumptions about the risk's existence;

- Gather relevant background information and/or data on the potential danger, damage, or impact on human health related to the risk evaluation;
- Appoint a leader and required resources;
- Establish a schedule, expected outcomes, and the appropriate level of decision-making for the risk management process. (8)

4.3 Risk Assessment

Risk evaluation involves pinpointing dangers and examining and judging the risks linked to being exposed to these dangers (as outlined below).Effective risk evaluations start with a clearly stated problem or risk inquiry. Once the risk in question is clearly stated, it becomes easier to identify the right risk management method (see examples in section 5) and the kind of information required to tackle the risk inquiry. To better understand the risks for the purpose of risk evaluation, three key questions are often useful:(9)

Risk identification: Identifying risks involves systematically gathering information to pinpoint potential dangers related to the risk question or problem at hand. This information can come from historical records, theoretical studies, expert opinions, and the perspectives of those affected by the issue. The goal of risk identification is to answer the question, "What could possibly go wrong?" by identifying potential outcomes. This step lays the foundation for the subsequent phases of the risk management process. (9)

Risk analysis: the process of determining the level of risk associated with the identified hazards. It involves assessing the likelihood of an event occurring and the severity of its impact. In some risk management methods, the ability to detect the occurrence of an event (detectability) is also considered in this analysis. (9)

Risk evaluation: involves comparing the risks identified and analyzed with established risk criteria. This step looks at the strength of evidence for the three main questions: What could happen? How likely is it to happen? What would be the impact? Risk evaluations take into account the quality of evidence for each of these questions. For a risk assessment to be effective, the reliability of the data used is crucial as it affects the quality of the results. It's important to disclose any assumptions made and to identify credible sources of uncertainty to increase confidence in the results or to highlight limitations. Uncertainty arises from a lack of complete understanding about a process and its expected or unexpected outcomes. (10) The results of a risk assessment can be either a numerical estimate of risk or a qualitative description of a range of risks. If risk is quantified, a numerical probability is assigned. Otherwise, risk can be described using qualitative terms like "high," "medium," or "low," which should be as detailed as possible. Sometimes, a "risk score" is used to further refine risk descriptions in risk ranking. In quantitative risk assessments, a risk estimate provides the likelihood of a specific outcome given certain risk-generating conditions. Thus, quantitative risk estimation is particularly useful for focusing on one specific outcome. On the other hand, some risk management tools use a measure of relative risk to aggregate multiple levels of severity and probability into an overall estimate of relative risk. The steps in a scoring process may also involve quantitative risk estimation. (10)

4.4 Risk Control

Risk management involves making decisions to either minimize or accept risks. The goal of risk management is to lower the risk to a tolerable level. The effort invested in risk management should be in proportion to the importance of the risk. Decision makers may employ various methods, such as benefit-cost analysis, to determine the best approach for risk management. Risk management may address the following questions: (11)

- Is the risk exceeding an acceptable threshold?

- What steps can be taken to lessen or remove risks?
- What's the right balance between benefits, risks, and resources?
- Do new risks emerge as a consequence of controlling the identified risks?

Risk reduction: In terms of risk management, reducing risks focuses on strategies for minimizing or avoiding risks when they surpass a certain (tolerable) level (refer to Fig. 1). Strategies for reducing risks may include actions aimed at lessening the impact and likelihood of harm. Methods for enhancing the ability to identify hazards and risks in quality management may also be utilized as part of a risk management approach. Implementing risk reduction strategies can introduce new risks into the system or heighten the significance of other existing risks. Therefore, it may be necessary to reassess the risk after implementing a risk reduction strategy to identify and evaluate any changes in risk levels. (11)

Risk acceptance: involves choosing to acknowledge the risk. Risk acceptance can be a formal decision to accept the remaining risk or it can be a passive approach where the remaining risks are not clearly defined. For certain types of damages, even the most effective quality risk management practices may not completely eliminate risk. In such cases, it might be agreed that an appropriate quality risk management strategy has been applied, and that the risk has been reduced to a specified (tolerable) level. The specific level of risk that is considered tolerable will vary based on several factors and should be determined on a case by-case basis. (12)

4.5 Risk Communication

Risk management involves making decisions to either minimize or accept risks. The goal of risk management is to lower the risk to a tolerable level. The effort invested in risk management should be in proportion to the importance of the risk. Decision makers may employ various methods, such as benefit-cost analysis, to determine the best approach for risk management. (13) Risk management may address the following questions:

- Is the risk exceeding an acceptable threshold?
- What steps can be taken to lessen or remove risks?
- What's the right balance between benefits, risks, and resources?
- Do new risks emerge as a consequence of controlling the identified risks? (14)

In terms of risk management, reducing risks focuses on strategies for minimizing or avoiding risks when they surpass a certain (tolerable) level . Strategies for reducing risks may include actions aimed at lessening the impact and likelihood of harm. Methods for enhancing the ability to identify hazards and risks in quality management may also be utilized as part of a risk management approach. Implementing risk reduction strategies can introduce new risks into the system or heighten the significance of other existing risks.(15) Therefore, it may be necessary to reassess the risk after implementing a risk reduction strategy to identify and evaluate any changes in risk levels. Risk acceptance involves choosing to acknowledge the risk. Risk acceptance can be a formal decision to accept the remaining risk or it can be a passive approach where the remaining risks are not clearly defined. For certain types of damages, even the most effective quality risk management practices may not completely eliminate risk. In such cases, it might be agreed that an appropriate quality risk management strategy has been applied, and that the risk has been reduced to a specified (tolerable) level. The specific level of risk that is considered tolerable will vary based on several factors and should be determined on a case-by-case basis**.** (16)

4.5 Risk review

Managing risks should be an integral component of the quality assurance procedure. It's necessary to establish a system for evaluating or overseeing occurrences. The outcomes of the risk management procedure need to be examined to incorporate fresh insights and experiences(17). After initiating a quality risk management strategy, it's important to keep applying it to any situations that could affect the initial risk management choices, whether these situations are scheduled (like the outcomes of product evaluations, inspections, audits, or changes) or unexpected (like the cause of a failure, a recall). The regularity of these reviews should be determined by the risk level. Risk evaluations may involve revisiting decisions on whether to accept risks (18).

CONCLUSION

Risks to the drug product's quality are evaluated, controlled, communicated, and reviewed systematically throughout the product lifecycle through the use of quality risk management. Regulations can be more assured of a company's compliance with the law if quality risk management is implemented effectively. Capacity to manage possible hazards, which could influence the scope and degree of direct regulatory supervision.

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