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Quality Risk Management: A Demand of Pharmaceutical Industry

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Abstract— In fish ponds, the quality of water must be monitoring with the help of Wireless sensor networks. In

The Quality Risk Management policy is being successfully implemented in many areas of business and government including finance, occupational safety and public health, chemical and pharmaceutical regulatory agencies. ICH Q9 was widely used to improve risk-based approaches or risk management policy within the pharmaceutical and environmental regulatory industry. The basic risk management process involves the level of effort, composition and documentation associated with the level of risk and risk assessment should be based on scientific knowledge. An effective disaster risk management approach can further ensure the high quality of the patient's (medical) product by identifying and controlling potential quality issues during development and operation. Ensuring product quality and ensuring the availability of essential medicines is essential in the science of manufacturing to keep pace with advances in pharmaceutical R&D. The disaster risk management process should be based on disaster risk analysis, identification and evaluation and disaster risk management plans that should be reviewed after compliance. This paper represents the result of a summary of quality control over the general principles of disaster risk management and best practice. Quality Risk Management supports a scientific and practical approach to decision-making.

INTRODUCTION

The Disaster Management System is being used effectively in many areas such as business and government including public health, occupational safety, insurance, medical assistance etc. an important quality of an effective quality system. An accident

is defined as the combination of the chances of injury occurring with the magnitude of the damage. However the use of disaster risk

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management is difficult to understand because each of the participants can look at different potential injuries, set different expectations and different sizes. In the case of therapeutic drugs, although there are a variety of stakeholders, including patients and physicians as well as government and industry, patient safety by managing quality risk should be considered the most important.[1, 2, 13-23]

The production and use of a drug product, including that requires a certain level of risk. It is important to understand that product quality must be maintained throughout the life cycle of the product so that the essential qualities of product quality remain consistent with those used in medical studies. [1]

An effective disaster risk management system provides a high level of product assurance to the patient by providing effective means of identifying and controlling potential quality issues during product and production. [17-20]

Scope:

This paper provides guidelines, procedures and examples of risk management tools that can be used in various aspects of medical quality. These include the manufacture, production, distribution, and lifetime testing of drug products, biological and biotechnological products (including consumer, solvents, raw materials, packaging and branding of drugs, biological and biotechnological products). [1, 2, 3]

Principle: Two primary principles of quality risk management: [1, 3, 4]

- The assessment of the risk to quality should be based on scientific facts and eventually link to the safety of the patient; and
- The level of strength, formality and documentation of the quality risk management process should be adequate with the level of risk.

General Quality Risk Management Process

Risk management is an efficient process of evaluating, controlling, communicating and reviewing risks to drug product quality throughout the product life cycle. The risk management model is shown in Fig. 1.

Responsibility:

In the medical field, risk management teams are formed and include specialists from the relevant areas for example quality units, business development, engineering and clinical as well as a person with expertise in the standard risk management process.[1] The decision maker assumes the entire responsibility for quality control in the various departments of their organization. [1]

Implementing a quality risk management process: [1, 2, 4]

Risk management should have systematic processes aimed at coordinating, simplifying and improving scientific-based decision-making about risk. Steps that can be used to start and plan a quality risk management process may include the following:

Describe the problem and / or question of risk, including relevant assumptions;

- Include background information and / or data on potential risks, or human health implications associated with risk assessments;

Identify the leader and resources needed;

- If you specify a timeline, time and appropriate level for making decisions about the risk management process.

Risk Assessment: [1, 2, 4]

This is the first step in risk management which includes risk identification and analysis and risk assessment associated with exposure to risks. It primarily begins with a description of a well-defined problem or question of danger. The risk assessment process clearly defines risk with the help of three key questions: A. What could go wrong? B. What are the chances of it going wrong? C. What are the consequences?

Risk Identification: [1, 2]

Where systematic use of data (including historical data, opinion analysis has informed opinion) to identify the risk in question of risk. Risk

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identification mainly addresses the question of "What could go wrong" and its consequences. Fig. 2

Risk Analysis: [1, 2, 4]

It involves measuring the risk associated with the identified risk. Risk analysis is the process of measuring and measuring the likelihood of emergence, severity and risk.

Risk Assessment: [1, 2, 4]

It compares the risks identified and analyzed compared to the prescribed risk model. The risk assessment looks at the strength of its evidence in all three key questions. The result of a risk assessment can be a measure of the magnitude or severity of an accident. When risk is expressed in large numbers the chances of using numbers are greater. And when the risk is indicated by quality the definition is given as "high, medium, low" and is described in as much detail as possible. The risk assessment looks at the strength of the evidence in all three key questions. (Figure 1)

Risk Management: [1]

Risk management involves a variety of decisions to reduce and adopt risk. The main purpose of risk management is to reduce the risk to an acceptable level. Decision makers can use a variety of processes, including cost analysis, to understand the appropriate level of risk management. [5]

Risk management may focus on the questions: A. Is the risk higher than acceptable? B. What can be done to reduce or eliminate risks? C. What is the right balance between benefits, risks and resources? D. Are there any new risks introduced as a result of identified controlled risks?

Reduce Risk: [1]

It basically includes procedures to reduce or avoid quality risks as they increase to an acceptable level. It can include the act of reducing the severity and risk of injury. Procedures that promote risk identification and quality risks can also be used as part of a risk management strategy.

Implementing risk mitigation measures may introduce new risks in the system or increase the number of other risks available to review risk assessments to identify and evaluate any potential changes in risk after initiating the risk reduction process.

Acceptance of Risk: [1, 2, 8]

It means the decision to accept the risk. Acceptance of risk can be a legitimate decision to accept risk because best disaster risk management strategies may not completely eliminate risk so that quality risk is reduced to a level.

Risk Communication: [1, 6, 8]

Risk communication includes the sharing of information about identified risks and risk management between the decision maker and others. Risk communication is done at any stage of the risk management process. It mainly involves the product / output release of a quality risk management process. Communication mainly includes regulators and industries, industries and patients, within the company etc. It is widely used to manage information regarding any risk and its acceptance in the industry. [5]

Risk Review: [1]

Risk reviews mainly include the release or outcome of a risk management process to look for new information and experience. Where a high-risk risk management system has been implemented that policy should continue to be used for events that may influence the initial risk management decision, whether these events are planned or not.

Risk Management Methods and Tools

Regular and reliable reviews of some of the basic tools that can be used in industry risk management and regulators, References are included to add more details and details about a particular tool. It is important to note that no single tool or set of tools works in all cases where the risk management process is used.

Ways to Promote Risk Management: [1]

The most common approaches used to plan risk management by data planning and assisting in decision-making are:

- Flowcharts;
- Check Spreadsheets;
- Map Editing;
- Cause and Effect diagrams / Ishikawa diagram.

Failure Mode Effect Analysis (FMEA)

Failure Methods and Outcome Analysis methods designed to identify product or process failures prior to problems, risk assessments.[5] Provides an evaluation of the potential failure of processes and their effect on product performance, provided that failure methods are identified, risk reduction can be used to eliminate, contain, reduce or control potential failures. . It is a powerful tool to summarize the main causes of failure, the factors that cause this failure and the possible consequences of this failure. It can be used for equipment and services and can be used to analyze production work and its effect on a

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product or process. The FMEA release can be used as a basis for further construction or analysis or directing of resource deployments. [1, 2]

Failure Mode Effects and Criticality Analysis (FMECA)

It is an extension of the FMEA tool mentioned above. Expand the FMEA to include an investigation into the magnitude of the effects, the likelihood of its occurrence, and its availability through Failure Mode Effect and Criticality Analysis. [1] FMECA can identify areas where additional safety measures may be appropriate to reduce risks. In FMECA, each mode of product failure is identified and value-tested. This risk translates into risk, and if this level of risk is not acceptable, corrective action should be taken. [7] FMEA or FMECA are often required to comply with safety and quality requirements, such as ISO 9001, QS 9000, ISO / TS, Six Sigma, Security Management, FDA Good Production (GMPs) 8 FMECA may be used for failures and accidents associated with production processes; however, it is not limited to this application. The effect of FMECA is the risk of "measuring" in each failure mode, which is used to measure the risk paths. [1]

Problem Tree Analysis (FTA)

This tool detects product or process failures. The FTA tool detects system failures simultaneously but can cover multiple causes of failure by identifying sub-chains. The result of the FTA is indicated by the wrong tree shape. At each level in the tree, a combination of faulty methods is defined by rational workers. [1, 9]

It can be used to establish a path to the root cause of failure. This can be used to investigate complaints or deviations to better understand the cause and to ensure that the intended improvement will solve the problem and not create another problem1 alternative. Error tree analysis is an effective tool for assessing how many factors affect a given problem. It is useful for both risk assessment and monitoring systems. [10]

Risk Analysis and Key Control Points (HACCP)

HACCP is a structured, efficient, and secure tool to ensure product quality, reliability and safety. It is a systematic approach that uses technological and scientific principles to analyze, evaluate, prevent, and control risks or adverse effects of hazards resulting from the manufacture, development, production and use of products. [1, 11]

HACCP has the following seven steps:

i. Perform a risk analysis and identify ways to prevent each step of the process;
ii. Determine sensitive control areas;
iii. Set sensitive limits;
iv. To establish a system for monitoring critical control areas;
v. To establish remedial action to be taken when monitoring indicates that sensitive control areas are not in a state of control;
vi. Set the system to ensure that the HACCP system

HACCP can be used to identify and manage risks associated with physical, chemical and biological hazards (including microbiological contamination). HACCP analysis involves the determination of critical points not only in the production process but also in other phases of the life cycle. [1]

Risk Performance Analysis

This is based on the assumption that dangerous events are caused by deviations from construction or operational objectives. It is a systematic process of risk assessment using word-of-word guidelines. "Directing Names" such as No, More, Other Than, Part of, etc. used in appropriate parameters (e.g., contamination, temperature) to help identify potential deviations from normal use or for construction purposes.[12-17] HAZOP can be used in manufacturing programs, including outdoor production and construction and by promoting suppliers, equipment and equipment for drug and drug products. As in HACCP, the result of the HAZOP analysis is a list of critical disaster risk management activities. [1]

Initial Risk (PHA)

A PHA is an analytical tool built on the use of prior risk information to identify future risks, risk factors and possibly hazardous events, and to calculate the probability of a assumed item, location, product or system. [13-15]

This tool contains:

i. Identifying the probability of an accident,
ii. Quality assessment of the level of injury or potential health damage that may occur again,
iii. A consistent position of risk using a combination of complexity and probability of occurrence,
iv. To identify remedial measures,

It can be useful when analyzing existing systems or prioritizing situations where circumstances prevent the full process from being implemented. PHA is widely used at the beginning of development when there is little knowledge of construction details or operating procedures; therefore, it will usually be a precursor to further studies. [14-15]

Risk Level and Filtering

Risk level and filtering is a tool for comparing and risking risks. The complexity of complex systems requires an examination of the various sizes and dimensions at each risk. The tool includes separating the basic risk question into as many items as needed

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in order to determine the factors involved in the risk. [2]. Risk and filtering can be used to prioritize production facilities for inspection by regulators or industry. It is useful in a situation where the risk portfolio and the basic outcomes to be managed are different and difficult to compare using the tool. Statistical tools can support and simplify the risk management system. They can allow for effective data testing, help determine the number of data sets, and facilitate reliable decision-making. [16-18] List of some of the most widely used mathematical tools in the pharmaceutical industry approx:

- Manage Charts, for example: Admission Control Charts; Manage Charts with Arithmetic Rate and Warning Limits;
- Experimental Design (DOE);
- Records;
- Pareto Charts;

Implementation of Quality Risk Management: [22-23]

Documents: Assessing current interpretation and application of control expectations.

Education and Training: Determining the accuracy of initial and / or continuous training sessions based on the education, experience and conduct of staff, as well as periodic evaluation of previous training.

Lack of Quality: Provide a basis for identifying, evaluating and informing the potential impact of suspected quality assumptions, deviations, investigations, due to implied results, complaint, filing, etc.

Evaluation / Evaluation: Defining the scope and scope of auditing, internally and externally, taking into account factors such as:

- Site complexity; Compliance General compliance status and company or institutional history;
- Strengthening the company's risk management activities; Requirements Existing legal requirements;
- The complexity of the production process;

As part of the Control Task: Monitoring and Evaluation Tasks: Assisting with resource allocation includes, for example, quantitative assessment and planning, robustness and dynamic testing.

Risk identification should be communicated to inspectors and inspectors to facilitate a better understanding of how risks can be managed or controlled. As part of the development: Designing a quality product and its production process to continuously deliver the intended product performance and improve product performance information on a variety of materials, processing options and process parameters; Reducing variability in quality indicators: Reduce product and material defects; Reduce product. [4]

For Facilities, Equipment and Utilities:

Equipment, Equipment and Equipment: Building / equipment construction: Determining suitable locations for designing buildings and equipment, e.g. clean rooms compared to isolator technology; logistics; to reduce pollution. Determining suitable product contact materials for equipment and containers (e.g., choice of stainless steel range, gaskets, lubricants);

Institutional hygiene features: Protecting the product from environmental hazards, including chemical, microbiological, and physical hazards (e.g., deciding clothing and appropriate clothing); Mechanical cleaning and environmental controls: Separated efforts and decisions based on targeted use (e.g., batch compared to continuous production); Institutional suitability / equipment / equipment: Determining the size and quantity of institutional qualifications, buildings, and manufacturing equipment and / or laboratory equipment (including measurement methods). [6, 8, 19]

As part of asset management:

Monitoring and evaluation of contractors and contractors: Providing a comprehensive evaluation of suppliers and contractors.

Consumption of materials: Determining whether it is appropriate to use separate equipment (e.g., internal processing)

Conditions for storage, storage and distribution: Evaluate the adequacy of arrangements to ensure the maintenance of proper storage and transport conditions (e.g., temperature, humidity, container composition);

Prerequisites: Assessing the differences and potential quality risks associated with a variety of priorities (e.g. method of integration).

As Part of Product:

Verification: Identify size and size of verification, qualification functions and verification functions (e.g., analytical methods, processes, resources and cleaning methods;

Product Planning: Determining appropriate product planning (e.g., Commitment, campaign and successive production process processes).

Sampling and testing: Frequency testing and the power of continuous control tests (e.g., justifying reduced tests under guaranteed control conditions);

As part of the Laboratory Management and Stability Management:

In addition to the results of the specifications: Identify possible causes and corrective actions during the investigation of the specification results.

Delivery time / expiration date: Adequate storage and intermediate storage testing, connecting materials and startup items.

As Part of Packing and Labeling

Package design: Creating a second package to protect the main product of the package (e.g., product validation, label reading).

Closure plan selection: Determining critical container closure system parameters.

Label controls: Designing label control procedures according to the mixing power that includes different product labels, including different types of the same label. [19]

CONCLUSION:

The importance of a quality plan has been recognized in the pharmaceutical and patient protection industry by managing quality risk given high priority. QRM is important to understand that product quality should be maintained throughout the product life cycle. Risk management can be done with well-known management tools and integrated tool support, making it easy to implement high quality risk management principles. An effective disaster risk management system assists decision-making and provides FDA regulators with greater assurance, of the company's ability to deal with potential risks.

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Figure 1: Overview of quality risk management.

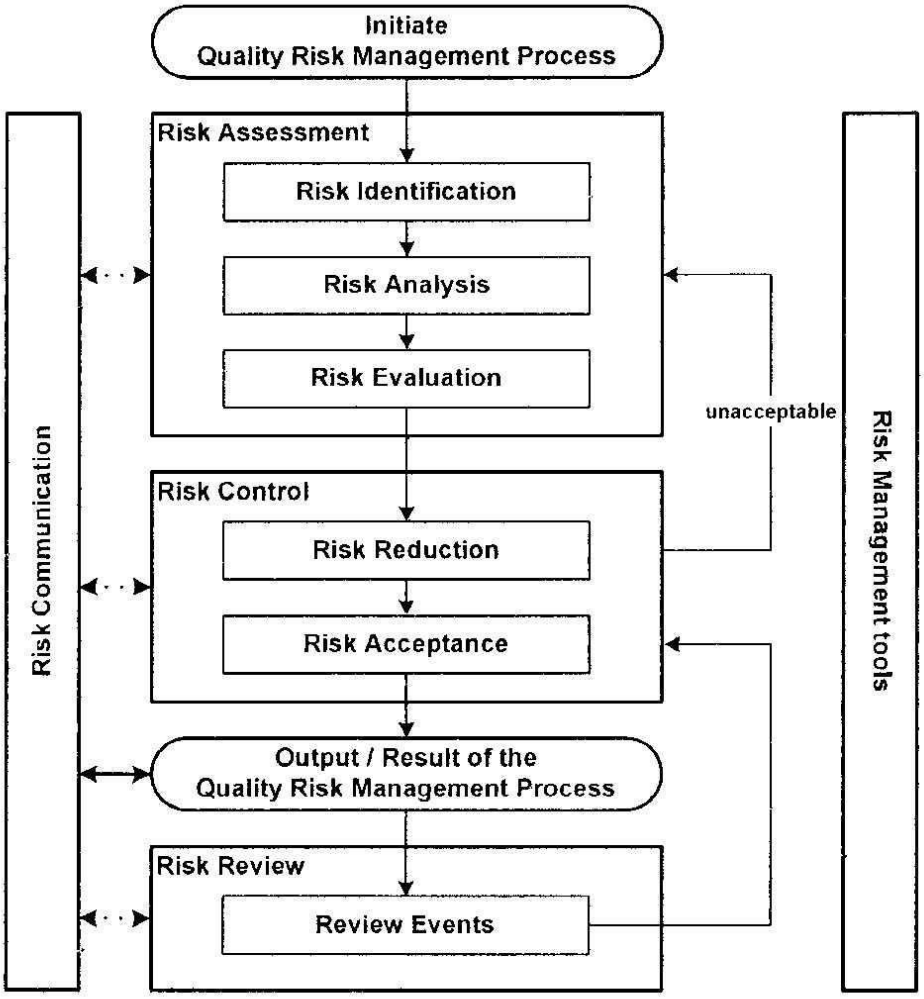

Figure 2: Picture of life cycle – Risk Analysis