A REVIEW ON PHARMACEUTICAL QUALITY MANAGEMENT SYSTEM

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ABSTRACT

International Conference on Harmonization, or ICH, refers to efforts to standardise the processes involved in registering new drugs for use in humans. Data on ICH, its activities, or guidelines is made public so that the three ICH regions (the United States, Japan, and also the European Union) can collaborate to discuss and adopt common norms. In recent years, the regulations governing the release of generic pharmaceuticals have taken on greater significance. The pharmaceutical industry is increasingly international in scope, from research to production. In this day and age, harmonisation is more important than ever because it facilitates the distribution of labour, the efficient use of resources, and the availability of life-saving medications. As well as ensuring quality, safety, and efficacy safeguards, the purpose of harmonisation seems to be to improve the use resources (human, animal, or otherwise) and avoiding needless delays in the global rollout of new drugs. The current review is centred upon Quality Risk Management in relation to the ICH quality control recommendations (Q9). In order to guarantee quality assurance for a finished item or service, quality control is employed. It could include everything an organisation deems necessary for the effective administration and assurance that their procedures are correct. attributes of a good or service Typically, this means conducting extensive inspections and tests to ensure that products and services are of the highest quality. The fundamental goal of this procedure is to ensure that the offered goods and services are reliable, user-friendly, secure, and sustainable. Risks to the quality of a drug product are constantly present throughout the product's lifecycle, and quality risk management is a methodical approach to identifying, mitigating, communicating, and reviewing these risks. There needs to be a solid foundation in science and a direct correlation to the patient's safety in order for the risk assessment to be reliable; and Quality risk management should be conducted with the amount of effort, formality, the documentation that is appropriate for the degree of risk.

Keyword : Quality Risk Management(Q9), ICH , Quality Control, Drug Development.

INTRODUCTION

Organizations in Europe, Japan, and also the United States that are in charge of regulating the pharmaceutical sector have joined forces to create ICH. Procedures for evaluating and guaranteeing the quality, safety, and effectiveness of the medications, including discussions of the relevant scientific and technical factors involved. Technical Requirements for Human Pharmaceutical Registration: International Conference on Harmonization (ICH) (1)

AIM

To better the effectiveness of the work via harmonisation, ICH was established in 1990 as just a joint effort between regulators and the pharmaceutical sector. formulation and submission for approval of innovative pharmaceutical products in the European Union, Japan, and also the United States Facilitating the speedy distribution of pharmaceuticals to the general population (1)

Need of ICH

Industry in the pharmaceutical sector was striving to expand its advertising reach internationally at the time. The United States, Europe, plus Japan were identified as the top three pharmaceutical markets. Japan is part of the "Triad." Despite the fact that all three Drug regulatory approval procedures, as well as thos were founded on the same ideals. This implies-The precise technical specifications in each region differed (1).

HISTORY

In 1980, the EU took the initiative to harmonize regulatory standards. Parallel to the 1989 Bilateral negotiations between Europe, Japan, and the United States on the possibility of harmonisation surfaced during the WHO Congress of Drug Regulatory Authorities in Paris, where early plans for action were addressed. Following EFPIA (European Federation of Pharmaceutical Industries and Associations) was contacted by authorities to explore a collaborative regulatoryindustry effort on worldwide harmonisation.

ICH Gudelines and Goals

Q'- Quality Subjects, i.e., QA in the Chemical and Pharmaceutical Industries.

Pre-clinical studies in vitro and in vivo,

"S," stands for "safety topics."

Topics beginning with a "E" are those that focus on efficacy, such as those investigated in human clinical trials.

Topics that cut across traditional academic disciplines, denoted by the letter "M, from the aforementioned group and the ICH's core missions are:

- To keep an eye on, keep up, and enhance the harmonisation of technical standards around the world.
- Medicines need to be developed and approved in the most economical and time-efficient way possible to ensure their safety, efficacy, and quality.
- The goal is to improve and secure public health on a global scale.
- Human clinical trials should not be repeated unless absolutely necessary.
- Without compromising safety or efficacy, lessen the number of times animals are used in scientific experiments.
- To improve the efficiency of drug development around the world (1)

Q9- QUALITY RISK MANAGEMENT

Definition of Quality

The extent to which a product, system, or process's intrinsic features meet requirements.

Management

Risk management in the pharmaceutical industry is the process of identifying, mitigating, reporting, and analysing any threats to a drug's quality at every stage of its development.

Risk

It is a combination of the likelihood of harm occurring and the severity of that harm.

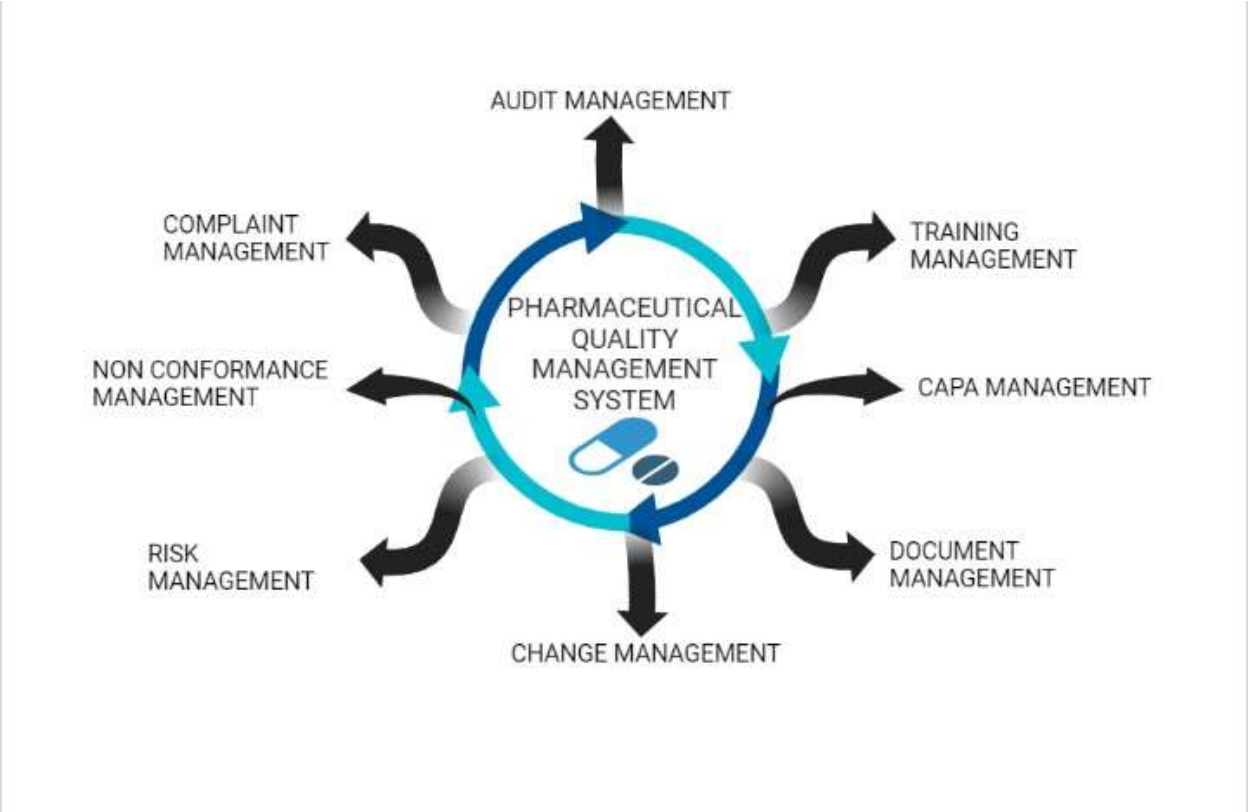

Figure : 1Schematic Diagram of Pharmaceutical Quality Management System

PRINCIPLES OF QUALITY RISK MANAGEMENT

Scientific understanding and the formation of a two-pronged approach to patient protection should be at the centre of any risk assessment; and Quality risk management was more involved, formal, and documented as the amount of risk rises. Quality risk management concepts and examples applicable to various stages of pharmaceutical production are presented in this advice.

PROCESS OF QRM

RISK MANAGEMENT METHODS AND TOOLS

1.Basic Risk Management Facilitation Methods

The basic approaches used it to Framework risk management involve grouping data and The following factors aid in decision-making:

2. Failure Mode Effects Analysis (FMEA)

FMEA analyses potential sources of failure in a process and how that failure could affect the results, product dependability, or overall efficiency.

Potential Areas of Use

FMEA can be used to prioritize risks and track the effectiveness of risk management activities.

3.Failure Mode, Effects and Criticality Analysis (FMECA)

Failure Analysis of Mode, Effects, and Criticality (FMECA) was a more in-depth variant of FMEA that considers not only the likelihood of specific results but also the severity and detectability.

Potential Area of Use(4)

Implementing FMECA in the pharmaceutical business is largely for the purpose of identifying and mitigating risks associated with production.

4.Analysis of Fault Trees (FTA)

An example of a technique that presupposes the inoperability of a system is the FTA tool. anything created or done Even though this method evaluates system (or subsystem) faults individually, it may combine several reasons of failure by following their chains of causation (5)

Potential use of Use

Research may make advantage of FTA. the origin of any problems or discrepancies, and make sure everyone is on the same page the proposed enhancements will be completely implemented address the problem without causing more problems difficulties (for example, solving one problem while causing another) a distinct issue). Analysis of Fault Trees is a useful tool for determining how A given issue is influenced by a number of elements.

5. Hazard Analysis and Critical Control Points (HACCP)

It's a systematic approach that uses technical and scientific concepts for figuring out what's going on and how to fix it. the potential for harm or unintended consequences due to hazards in product development, production, and usage (6)

HURDLES IN ABSENCE OF QRM

- The lack of a universal approach to risk management may have negative effects on consumers, authorities, and businesses.
- The possibility of an unfit product being released onto the market is raised.
- The introduction of a brand-new product There is a chance that market may be late.
- Potential setbacks during times of transition and process enhancement.
- Potentially, we could create medicines that are both effective and safe.
- Manufacturers may be cautious to release cutting-edge technologies or make constant improvements to products and processes for fear of having them yanked from market or recalled. Limited means may be wasted. Allotted Data insufficiency prevents accurate risk evaluation
- Issues to be Resolved
- Effective and continuous use of terminology, including terms and quality, hazard, and risk assessment, among some other things, into choices relating to product quality and the impact it has on the patient is essential. Explain your situation in the application.
- Not a single risk management theory is workable or even tolerable.
- Principles of Risk Identification
- As a term, "management" is widely used in the business world.
- Information flows across and among sectors in terms of how much, what kind, and when it is shared and authorities all around the globe
- What It Takes to Keep the Peace and Get Along With the
- Environment Working Group and Drug Discovery
- Establishing roles and duties for government agencies and business actors, including
- Can risk be included into decisions about where to allocate resources

Benefits

- Assurance in pharmaceutical performance and decision has increased, benefiting both patients and healthcare providers. Increases efficiency by providing regulatory bodies and businesses with a more systematic, well-informed setting and thorough decision-making approach that yields more openness and predictability
- Improved awareness of potential dangers
- To promote excellence via design and ongoing enhancement.
- New and improved technologies
- Introducing a new feature typically leads to higher quality end outcomes.
- Increased autonomy and flexibility in the workplace

POTENTIAL APPLICATIONS FOR QUALITY RISK MANAGEMENT

1. Quality Risk Management as Part of Integrated Quality Management

Documentation

The goal is to assess how the rules are currently being applied and interpreted. for the purpose of determining the need for Standard Operating Procedures, Guidelines, etc., and/or developing their content.

Training and education

Training needs, staff working habits, and periodic evaluations of previous training are all considerations in determining the right mix of initial and continuing training sessions . Assessing whether or whether a worker has the education, experience, credentials, and physical ability to carry out a task consistently and without compromising the product's quality.

Quality Defects

A complaint, trend, deviation, investigation result, etc. that is outside of specification might serve as a starting point for identifying, analysing, and reporting the possible quality effect of the issue. on the product or service in question. To streamline risk communication and help authorities figure out how to fix serious product problems in line with regulations (e.g., recall).

Auditing/Inspection

To weigh factors like these when deciding how often and how thoroughly both internal and external inspections should be conducted:

- Given our current legal responsibilities,
- Overall compliance and regulatory status
- A background of the organisation or location corporate strength quality
- Some Measures Taken to Reduce Danger

Periodic Review

As part of product evaluation process, choose, evaluate, and understand data trend findings. In-Depth Measurement Data Analysis (to aid in determining whether revalidation or sample changes are required).

Change management/change control

- Managing transitions in light of knowledge and experience gained during the manufacturing of pharmaceuticals.
- Determine how the changes will impact the final product's accessibility.
- Analyze the effect that changes in infrastructure, inputs, or manufacturing methods have on final product quality.
- How extensive research, regulatory input, and/or testing is required before a change may be implemented.

2. Quality Risk Management as Part of Regulatory Operations

Inspection and assessment activities

- Help determine how many and how in-depth inspections, as well as how often, should be conducted.
- Concerns including quality concerns, possible recalls, and inspection outcomes.
- For the purpose of determining what kind of regulatory action should be taken after an inspection and whether or not it is necessary.

- For the purpose of evaluating data given by industry, particularly those pertaining to pharmaceutical research and development.
- To evaluate the results of proposed changes or modifications.
- In order to better understand how risks might be minimised or regulated (through methods like parametric release and Process Analytical Technology), it is necessary to recognize hazards that should be shared between evaluators and inspectors (PAT).

3. Quality Risk Management as Part of Materials Management

- In-depth analysis of contract manufacturers and wholesale distributors In order to thoroughly investigate vendors and outsource factories

Starting material

- The goal is to determine variations as well as the potential for excellence concerns caused by the variety of the input materials

Use of Material

- A determination of whether or not quarantined materials may be used (for example, for further internal processing).
- To determine whether it is reasonable to rework, repurpose, or recycle products.

Storage, logistics and distribution conditions

- To assess whether or not proper measures have been taken to ensure safe and secure storage and transportation how changes in storage or transit circumstances (such cold chain management) affect product quality.
- Repairs and maintenance of physical infrastructures
- The goal of this data offering is to guarantee medication supply

4. Quality Risk Management as Part of Production Validation
    - Determining the extent to which testing, inspection, and certification are performed
    - Find out how extensive the subsequent steps will be
    - Differentiating between important and noncritical phases of a process might help when planning research proving something to be true. (7)

In-process sampling and testing

Control parameters that have been proven may be used The purpose of this analysis is to determine the regularity and breadth of the in inspection procedures

- To assess and justify the usage of technologies for process analysis
- (PAT) in collaboration with Real-time and parametric release

Production Planning

- Optimizing production schedules (like single-tasking, multitasking, and simultaneous production).

5. Quality Risk Management as Part of Laboratory Control and Stability Studies

- Investigation to be vague or generalised outcomes Root causes and remedial measures may be determined throughout this process (8,9)
- Date of expiry or re-testing period
- To test and evaluate the viability of suitable storage conditions for raw ingredients, fillers, and binders.

6. Quality Risk Management as Part of Packaging and Labelling

Design of packages

Making an additional layer of packaging to safeguard already packed items

(A readable label and a genuine product.

Container Closure Method Selection

In order to properly seal a container, it is necessary to pinpoint the critical factors that govern the process.

Label controls

This project's goal is to develop label control strategies that allow for the risk of label confusion across several product labels, or even between various label iterations for the same product.

CONCLUSION

1. One Major Benefit to Patient Safety May Increase Quality Risk In addition That is executive comprehension. culture of regulation
2. Constant behavioral modification

- Identifying dangers can be beneficial.
- High quality capabilities thanks to thorough evaluation and management of a long list of recognised dangers
- Quality hazards must be recognized.- "Risk-based strategy"- Risks remain a possibility - No"Zero" Risk!

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CONFLICT OF INTEREST

Author declares that there are no conflict of interest.

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