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A Review of Total Quality Management in Pharmaceuticals

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ABSTRACT:

The implementation of an effective quality assurance policy is the most important goal of the pharmaceutical industry. The concept of quality assurance and quality control together advances in quality assurance, safety and effectiveness of pharmaceutical products. Therefore, quality is the most important ingredient in an organization's success today, which can be achieved through complete quality management (TQM), an organizational approach focused on quality as a highly focused goal, aimed at preventing mistakes rather than finding mistakes. It is the philosophy and development of an integrated quality management system that is internationally recognized in the pharmaceutical industry and other regulatory requirements. TQM's vision views quality as an important organizational goal. Current review efforts to provide a comprehensive view of TQM concept and management mean leading to improved quality of medicine.

Keywords: Total Quality Management[TQM], Quality by Design, International Conference on Harmonisation (ICH),Quality Management System, Quality Risk Management (QRM).

Introduction:

Features of the Quality Management System [1,2,4,6]

The laboratory is a complex system, which involves many stages of work and many people. The complexity of the system requires that many processes and procedures be performed correctly. Therefore, the quality management system model, which looks at the whole system, is very important in achieving good laboratory performance. The QMS is defined as 'a system of governance that governs and directs an organization in terms of quality. The QMS covers laboratory activities, which include drug sampling, analysis and reporting. The QMS contains policy documents and laboratory objectives, program procedures and instructions to ensure its quality.Today's world, the pharmaceutical industry is an integral part of the health care system, as it oversees the development and marketing of medical products, as well as the development of new medical products. social benefit. [2] Poor drug quality contributes to health problems and leads to significant financial and financial wastage in government and individuals. People are intelligent and are able to choose things that meet their needs. When it comes to the pharmaceutical industry, quality is one of the most important factors, and it gets a lot of attention because of the competitive environment. [4] As a result, quality preservation through continuous institutional development is vital to the pharmaceutical industry. [1] Regulatory agencies in several countries have identified certain flaws in the old quality management systems, and are committed to adopting this Total Quality Management (TQM) approach. The concept of total quality control was used in the early days, and quality was protected only based on the limits of quality control. However, because it contains complete records such as standard operating procedures for each step and step, verification records, master formula records, and collective production records, TQM covers the quality of construction during the manufacture of pharmaceutical product. [2]

Historical OverviewOfQuality Management[36]

The need for improved product quality arose in the 1980's, when it became apparent that the United States was following in the footsteps of some industrialized nations, especially Japan, in the area of product quality. Many of the tools and methods used to diagnose quality problems and take remedial action go back decades. For example, Walter A. Shewhart, a mathematician at Bell Labs, developed a set of methods in the 1920s designed to ensure the suspension and reduce of quality defects. His book "Economic Control of Quality", published in 1931, is still regarded as ancient. Joseph M. Juran was a mathematician who in the 1940s introduced the concept of "Pareto analysis", which states that 80 percent of all quality problems can be traced to a small number of causes. Phillip Crosby spent most of his career at the International Telephone and Telegraph. While there, Crosby wrote down the huge cost of repairing something that had not been done in the first place. His ideas were later published in the best-selling business "Quality Free". Arnand V. Feigenbaum developed the concept of "total quality control" in the 1940s, opposing the integrated quality development effort in all areas of work (eg procurement, finance, marketing) and not just in manufacturing and manufacturing. These ideas were also published in the book,

"Total Quality Control".

The introduction of Taylor's "scientific management system" leads to a strong division of labor and creates quality control on the basis of evaluations conducted by a specialized unit in the organization. Quality control involves the acquisition and disposal of final parts and products, which is not uncommon. It is a post-event process.The application of mathematical methods in sampling and testing has been produced to produce mathematical control methods (SPC). Quality control and testing focus on finding defective products, identifying products that do not meet their requirements and not allowing those out of the factory gate3,4. Two American quality graduates, Deming and Juran began to move and the concept of Quality Assurance followed by complete quality control (TQC) came into play. Quality assurance is about the first place and before and during the event process. The purpose of Crosby's statement is "zero defects". The bond is in the working capacity, usually working in groups or cells. TQC has been described as a "management framework to ensure continuity and efficiency". Here, 'Total' indicates that everything and everyone in the organization is involved in the pursuit of chastity. Also known as the Comprehensive Quality Control Company (CWQC). The USA facing the recession of the Japanese reconstruction economy, in the mid-'80s, recognized the quality and embraced this approach and called it the perfect quality service, strategic quality management, quality action, quality. first some of the TQM topics. An educational institution may use the title 'student first' or 'institutional development program' or any other topic as it feels appropriate.

Total Quality Management (TQM):[1,2,3,8,10]

TQM is an integrated approach to achieving quality at all levels and at all levels. TQM stands for "fulfillment of customer quality expectations." This is a customer-focused quality. [2] TQM is a new concept of quality control. TQM can be seen as value for money, ease of use, customer satisfaction, and commitment to quality. TQM is defined by the International Organization for Standards (ISO) as "an organizational structure, focused on excellence, based on the participation of all its members and aims for long-term success in customer satisfaction and benefits for all members of the organization. Organization and community." ISO 8402: 1994 [8] defines TQM as "an organizational, high quality management system, based on the participation of all its members and aims for long-term success in terms of customer satisfaction and benefits for all members. of product, it is the responsibility of many departments and processes at all levels to commit and ensure quality Achieving quality at all levels requires a concerted effort from the whole team, not just senior management. [3] This process of involving all departments working across the organization is very helpful in identifying and satisfying the needs of our customers. . , service, procurement, and quality store, i.e., finance, marketing, service, Only then will it be possible to ensure the perfect quality to work in partnership with the production department. Finally, due to the improvement of overall quality, the performance of the company will also improve. [10] Visual plant design, location, proper ventilation, hygiene and proper sanitation during product processing, strict implementation of standard operating procedures (SOPs), effective management of deviations and incidents, active participation of each team member in risk identification. and causes, effective CAPA management, and variability management, i.e.. As a result, total quality management (TQM) includes the following: [1]

• Customers should be satisfied first, all the time;
• Provide employees with the tools they need to solve problems and reduce waste;
• In addition to management, methodology, culture;

The key elements of the TQM approaches are following:

1. Focus on the customer: The most important organizational responsibility to identify customers (internal and external). Drug product customers can be foreign customers, while company employees may be internal customers. Organizations need to think again focus on what each customer expects, customer satisfaction as the main goal.

2. Employee Involvement Because quality is the responsibility of every employee, the organization must apply the knowledge and experience of each employee to the quality system better. The organization must involve all employees and urge them to participate actively in this movement to participate in quality development.

3. Continuous improvement: Improving quality and maintaining it is a never-ending process where each person contributes consistently to improving the performance of the company, production process, as well as product or service attributes. The goal of sustainable development is to periodically increase quality and maintain it. This will improve the overall situation product or service quality, as well as the overall business performance. [1]

Advantages of TQM

Improves dignity - errors and problems are identified and sorted quickly.
• High-quality senior staff motivated by increased responsibility, team performance and tqm involvement decisions.
• Low cost.
• Minimize waste as a few defective products and there is no need to separate.

Disadvantages of TQM

• Cost of initial introduction.
• Merits may not be apparent for a few years.
• Employees may not agree to change.

Quality management system:[29,30]

Quality management is defined as part of the administrative function that determines and implements the "quality policy", i.e. the overall purpose and direction of the organization regarding quality, as formally defined and approved by senior management.

The basics of quality management are:

a) Appropriate infrastructure or "quality plan", which includes organizational structure, processes, processes and resources

b) Systematic actions required to ensure that a product (or service) will meet the given quality requirements. The essence of these actions is called "quality assurance [29,30] (Figure 1).

Fig. PDCA Cycle

The Top Ten Responsibilities of PharmaceuticalQuality Unit [31]

a) Establish a quality system

b) Monitoring compliance with quality system

c) Establish procedures and details

d) Establish production controls

e) Performing laboratory tests or tests

f) Review and approve or reject all cGMP items

g) Ensuring non-compliance investigations

h) To keep managers informed

i) Defining responsibilities in writing

j) Staying independent

Quality:[13,14]

Quality is a term that is widely used but can be misinterpreted. Quality is an unusually smooth concept, easy to visualize yet difficult to describe. It is a matter of feeling and the meaning varies from person to person depending on the perspective described. Quality is defined in different ways by quality gurus such as - compliance with standards or specifications; suitability for use; to meet customer needs or expectations; to please the customer etc. The code defines 'quality and therefore the sum of the features and features of a product / service that is in line with its ability to meet the needs provided'2. When selecting a tablet to purchase, we will compare the different brands of that tablet on the basis of effective therapeutic efficacy and adverse effects, color and aroma. So the customer / user of the product makes a comparison of the features or qualities of the product and the lack of it, while comparing the quality. make the correct meaning of the word. The first is related to the features and attributes of the product or service. This ensures that the product or services meet the needs of the user. The second factor concerns the absence of defects in the product.

The eight quality standards, which are the most important ingredient in an organization's success, are as follows.

1. Performance: Key features of product performance.
2. Features: Additions to the product's basic functionality.
3. Reliability: The possibility of malfunctioning over a period of time.
4. Compliance: The level at which product design and performance characteristics meet the set standards.
5. Durability: Product life expectancy.
6. Service: Fast and easy adjustment.
7. Beauty: The way a product looks, feels, tastes and smells.

8. Visual quality: As seen by the customer.

Managing Quality System:[15,16]

It widespread method of quality management is called total quality management (TQM) - the organisation's real and effective attempt to change the whole way the business operates to make quality a guiding factor in everything the organization does. The main ingredients in TQM are discussed below3-5.

1. Strategic Commitment: The first area of TQM is strategic commitment to management (Fig. 1). Firstly the organization's culture needs to change to realize that quality is not just a virtue but a goal to be pursued. Second, the decision to pursue a quality goal goes hand in hand with real costs - costs such as new equipment and services. Therefore, without the commitment of senior management, quality improvement will be a slogan or a gimmick, with little or no real change.

2. Staff engagement: Staff engagement is another important ingredient in TQM. Almost all successful programs for quality improvement involve making the person responsible for the work responsible for ensuring that it is done properly. By definition, employee involvement is an important factor in improving quality.

3. Materials: Another important part of TQM is to improve the quality of materials used by the organization.

4. Technology: New technologies are also useful for TQM systems. Investing in a high-performance machine that can do the job very accurately and reliably often improves quality.

5. Method: Improved methods can improve product as well as service quality. The methods applications are used by an organization during a real transition process during the real transformation process

Pharmaceutical Quality Management System[5]

It operates in pharmaceutical products, including biotechnology and biological products, throughout the product life cycle systems that support the development and production of pharmaceutical substances. [5] Includes:

1. Medication Development

A. Production and development of APIs.

B. Development of medical equipment and equipment for investigation.

C. Development of medical delivery systems.

D. Assessing plant growth activities

E. The production process of molding

F. Development of accurate measurement medical systems

2. Development of an analysis method

A. During the production process

• Procurement and control of goods

• Provision of services, resources, and equipment

• Production (including packaging and labeling)

• Quality control and assurance

• Free

• Storage

B. During the transfer of product technology.

C. At the time of product discontinuation

• Saving of sample and related documents

• Ongoing product evaluation and reporting

Elements of a Quality Management System [32]

A quality management system usually consists of four components

a) Quality Planning: The process of translating quality policy into processes, procedures, and instructions to achieve measurable objectives and requirements.

b) Quality Assurance: Planned and operational tasks performed as part of a quality system to give confidence that the process, product, or quality service requirements are met.

c) Quality control: The act of monitoring, evaluating, and adjusting a process, product, or service to ensure that quality requirements are met.

d) Quality improvement: The process of evaluating performance and taking methodical, systemic actions to improve it.

International Conference on Harmonization [33,34]:

ICH is a collaborative program involving both Regulators and industry-based European, Japanese and US research programs for scientific and

technological discussions of evaluation processes;needed to evaluate and ensure the safety, quality and effectiveness of medicines. ICH stands for "International Consensus Conference" on Technical Requirements for the Registration of Medicines for Human Use.

ICH Q10:

ICH Q10 describes one comprehensive model of an effective pharmaceutical quality system based on the International Organization for Standardization (ISO). Concepts of quality, incorporating practical principles of good practice (GMP), and compliance. The use of ICH Q10 throughout the product life cycle should help to innovate and improve continuously and strengthen the link between drug development and manufacturing activities.

Aim:

ICH was established in 1990, as a joint regulatory / industrial program to develop, harmonize, process efficiency, development and registration of new pharmaceutical products in Europe, Japan and the US.

The purpose of the ICH

The basic purpose of the ICH is

a) Monitor, renew and increase international compliance with Technical Requirements.

b) Ensuring the safety, efficacy and quality of medicines to be developed and registered in the most efficient and cost-effective manner.

c) To promote as well as protect public health from an international perspective.

d) To prevent unnecessary duplication of clinical trials in humans.

e) Reduce the use of animal testing without compromising safety and effectiveness.

f) Improving the effectiveness of Global Drug Development.

Need of ICH:

The guide has helped to achieve consistency in the quality of products worldwide for the export of medicines without interruption at the international level.

Program for Testing in the Test Laboratory [34,35]

Experimental laboratory experts have shown a growing interest in understanding the QMS and gaining accreditation for their services since the introduction of international quality management system (QMS) standards. Quality assurance is therefore defined as the process or end of a process that ensures the integrity of the product to meet the intended use level. Quality assurance is a responsibility that is automatically placed on the manufacturer of any product to ensure that it meets the needs of the end user in the intended intended use. For the end user, a benchmark quality benchmark can not allow less than 100%.

Quality Risk Management:[11]

For us, risk management is not a new concept. In general, risk management is something we do all the time. Quality risk management is defined as a form of risk assessment, risk management, risk consultation, and risk review of drug quality. product It is a widely used tool in the pharmaceutical industry for drug risk assessment.

Risk Definitions:

The definition of a real accident dictionary is "chances of loss or injury". In simple words it is an unwanted result.

"According to the ICH Q9 guidelines it has a definition as a combination of possibilitiesdamage (unwanted effect) and magnitude of that damage ". [11]

Definition of Quality Risk Management: [11]

"It is a systematic process of assessing, controlling, communicating, as well as reviewing the risks of product (medical) product quality throughout the product life cycle."

QRM is made up of a number of features, including risk detection, data analysis, risk planning, risk monitoring, and risk management. These variables are shown in the diagram below.

Fig.Components of Quality Risk Management

Quality Risk Management includes:

Risk identification: Identifying risks before they become significant is important. We may use the expertise and knowledge of our employees to identify risks by encouraging them to participate in the program. The organization may ask everyone to identify any hazards they may have encountered while performing a specific task or process. During the process, the company may also ask the team to highlight any existing risks or potential risks in the future.

Data analysis: Once the team has compiled a list of all current and potential threats, risk data should be analyzed. During this process, the team will evaluate the likelihood of an accident occurring, and then evaluate the risk based on the impact of the accident or magnitude. As a result, we can prioritize risk reduction based on risk assessment. This process is alsocalled as risk assessment.

Planning: Once the risk level has been set and the importance of risk reduction is set, the organization should plan to reduce risk. To manage risks, a number of practical solutions must be identified, and a mechanism must be developed to reduce those risks.

Track: Once risk reduction plans have been identified, we need to be vigilant to better manage risk.

Control: This step involves keeping a close eye on programs designed to deal with risks. To achieve this, strong communication with the team and stakeholders is required to promote continuous monitoring and risk management. As a result, we may be able to eliminate or minimize the risks associated with our product.

Communication: Once the risk has been reduced, all information and conclusions from the Quality Risk Management System should be disseminated to all employees so that everyone is aware of the risks and the consequences of those risks. Thanks to this QRM process, organizations can deal with product risks while maintaining a high standard of their products and services.The following diagram shows the entire Quality Risk Management Process.

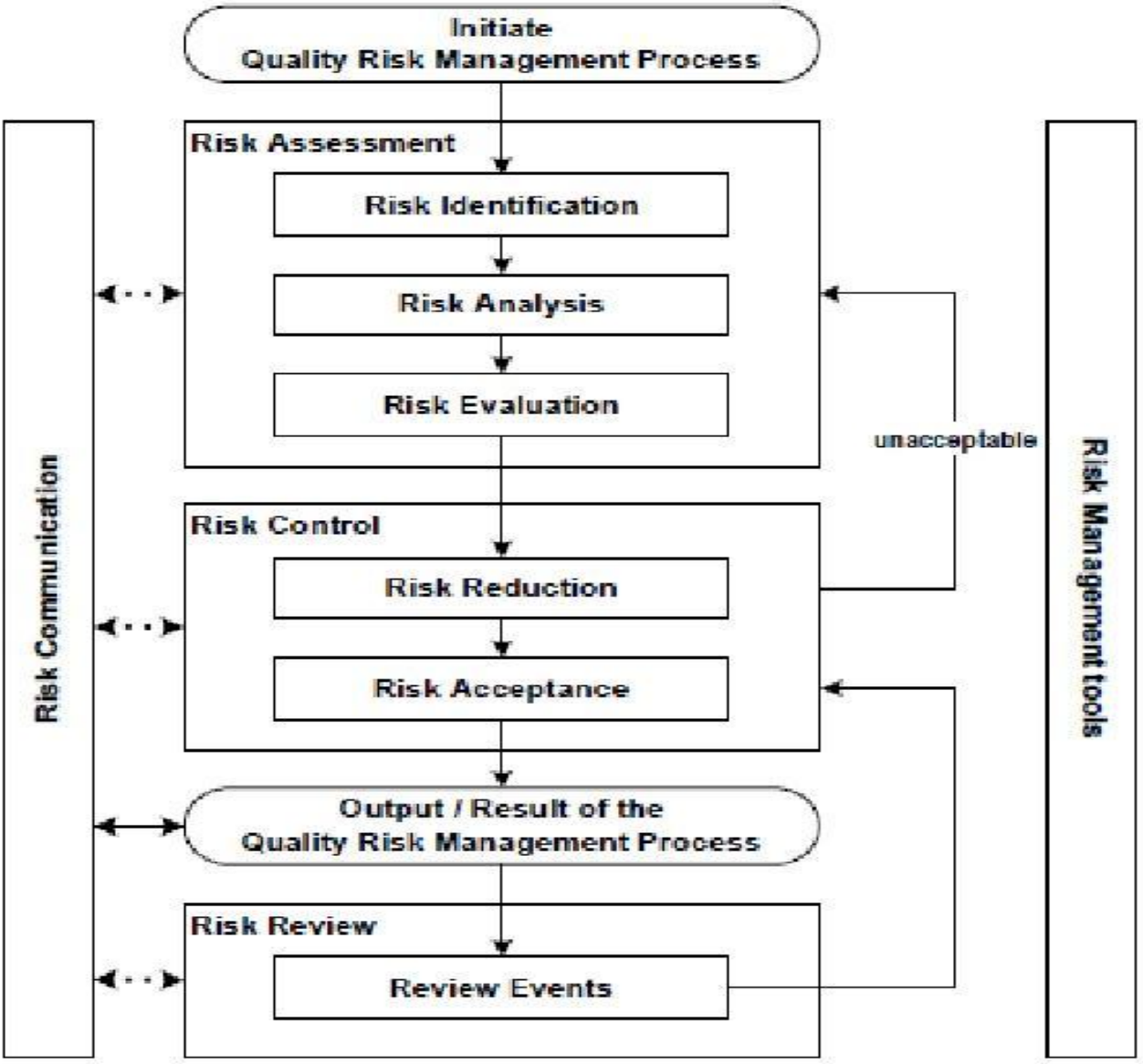

Fig. Typically Quality Risk Management Process

Quality by Design:[36]

Quality in terms of design changes the way managers think and conduct business. Loosely defined, quality by design is the practice of using a multi-sectoral team to create logical thinking, product design, and plan production all at once. They are also known as the same engineering, the same engineering, or the corresponding engineering. The team is made up of professionals from business, engineering, manufacturing, and customer base. Providers of processing equipment, purchased parts, and services are also included in the team at regular intervals. Quality by design has recently promoted changes in management structures. Some executives claim to have used it informally before it became popular.

Benefits of Quality by Design:

Because consumer trends drive market demand, an organization's ability to respond six months before a competition can significantly improve profits. Obviously, time is of the essence, but consumers will change brands if they can get the same product of the same quality for less money. In addition, if the product is not designed with cost in mind, inefficiency will eliminate the profits earned in the short lead times. Quality in design provides manufacturers with the tools and communication techniques needed to develop products in a timely and cost-effective way from the beginning and throughout the life of the product.The main advantage of using quality with design strategies is a significant reduction in marketing time. Some of the quality benefits of design strategies are:

Rapid product development.

Better quality.

A little work in progress.
A few orders for switching engineering.
Increased productivity.
The above benefits are also a basic reason for the reduction in product tagging time

Design of Six Sigma[36,37]

In the past, quality refinement by design has been developed and used by some companies around the world. This development is known as the "Design for Six Sigma" (DFSS). DFSS has been replaced by companies such as Motorola, GE, Cummins, Ford, John Deere to name a few. The DFSS roadmap is defined as follows.

• Explain the project objectives and customer offerings.
• Evaluate and determine customer needs and specifications.
• Analyze to generate new ideas, and explore and select the best design idea.
• Design details, design, and plan design validation and verification. This stage usually requires imitation.
• Ensure and ensure project integrity and ability to meet customer needs.

CONCLUSION:

TQM is the most effective way to control the quality of medicines. Many control themesstrongly advised, but not yet fully implemented in all businesses, especially in India. Because Indiaone of the world's leading retailers of pharmaceuticals, complete TQM adoption is essentialIndian setting. Despite significant advances in product development for real-time online productionpacking monitoring, low industrial use of this technology is still an important resourceanxiety. The article is a call to international regulatory agencies and the pharmaceutical industry for its stabilitystrengthening and true implementation of TQM methods in the industry to produce high qualitymedicines.

The manufacturer needs to know,

1) manage the causes of product quality variations, such as building materials, equipment, and processes such asand men
2) Make sure the best production methods and packaging methods are used.
3) Make sure the test results match the standards or specifications
4) With a well-designed and quality assurance system, ensure product stability and commitmentother functions related to product quality.Certain basic operating principles must be created and must remain applicable throughouta quality management system to operate efficiently. First and foremost, control decisions should be made purelyon the basis of product quality considerations. Second, performance must be strictly consistent with the rulesset standards or specifications as determined by formal tests, samples, and tests, as wellshould continue to try to improve current levels or levels of clarity. Third, employees must beaccess to the facilities, funds, and facilities they need to fulfill their responsibilities effectively. Lastlybut at least, in administrative matters, control choices must be independent, and should not be defeated orexcluded production or marketing under any circumstances. Because the decision to control mayaffects the health of the consumer and the dignity of the pharmaceutical manufacturer, the environmentwhat is needed to make informed decisions is essential. Only the highest level of proper managementcheck the control decision if there is a significant difference.

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