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Review Article

A Review On Quality Management System In Pharmaceutical Industry

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ABSTRACT

The quality management in pharmaceutical industry is important because of the quality of pharmaceutical product and drugs. QMS helps in pharmaceutical to improve the product quality and minimize the risk of product recall. product identity, purity, safety, and finally proper quality are extremely important or necessary. Product quality maintenance is a difficult process that requires consideration of several regulations, including GMP, GLP, and many more. Every pharmaceutical industry has a quality assurance section whose responsibility it is to determine whether or not the industries are follow the guidelines. he procedure by which they verify if everything is operating properly, either internally or externally, is called quality auditing.

INTRODUCTION

In the pharmaceutical industry, a quality management system is important to ensure the safety, efficacy, and reliability of medications. The concept of current pharmaceutical quality management system is based on a internationally harmonized ICH Q10 guidelines. These systems encompass stringent quality control measures at every stage of drug development, manufacturing, distribution, and post-marketing surveillance. comprehensive documentation, rigorous testing protocols, and adherence to regulatory requirements such as those set forth by agencies like the FDA (Food and Drug Administration) or EMA (European Medicines Agency). Such systems are vital to safeguarding public health and maintaining the integrity of pharmaceutical products. [1,2]

What is Quality in pharmaceutical industry – Pharmaceutical Quality Assurance is the assurance of quality requirements for a product or service in the pharmaceutical industry. Quality assurance aims to create and maintain customer confidence in the product, and the goal is to detect early or to prevent them. Quality assurance in the pharmaceutical industry is a continuous process that focuses on the constant review of customer requirements. [3]

Quality Management system (QMS) - Pharmaceutical Quality Management System (QMS) is a comprehensive collection of policies, processes, and procedures designed to ensure and

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maintain uniform and high quality in the production of pharmaceutical products. The QMS must reflect the specific needs of the pharmaceutical company and applicable regulatory requirements. It is relevant to pharmaceutical products, including biological and biotech products, and to the systems that enable the creation and production of pharmaceutical drug substances at stage of the product life cycle [1,4]

Figar No – 1 QMS In Pharmaceutical Industry

Objective –

The following three objective are the primary ones:

1. Successfully Realize the Product
2. Robust management of variables
3. Ongoing Improvement [5]

Elements of quality management system (QMS)-

A suitable framework, or "quality system," that includes the organizational structure, protocols, procedures and materials The methodical steps required to guarantee that a good (or service) will meet specified standards for quality. The word "quality assurance" refers to the sum of these actions.

Quality planning - The method of incorporating corporate policy into guidelines, protocols, and directives in order to obtain measurable goals and specifications. It is in this phase that companies define their baseline quality objectives. Once goals have been set, organizations must determine what is required to achieve these objectives and what procedures should be implemented to ensure their success.

Quality assurance - As a component of the quality system, plan the activities and their execution to ensure that the manufacturing of the products complies with quality standards. QA in the pharmaceutical industry involves implementing systems and processes to ensure that products consistently meet or exceed established quality standards. It encompasses activities such as Good Manufacturing Practices (GMP), quality management systems, and adherence to regulatory requirements.

Quality control - Quality control (QC) is a critical process in the pharmaceutical industry. It ensures that pharmaceutical products meet all applicable standards of quality, safety, and efficacy. Monitoring and corrective action taken to guarantee the creation of high-quality products

Quality improvement – First and foremost, continuous improvement is the cornerstone of quality excellence. By consistently refining processes, methodologies, and practices, organizations can ensure that their products not only meet but exceed the stringent quality standards set by the industry [6]

The Pharmaceutical Quality Unit's Top Ten Responsibilities

i. To put the quality system in place
ii. To verify that the quality system is being followed
iii. To set guidelines and requirements
iv. To set up guidelines for manufacturing
v. To conduct examinations or tests in a laboratory
vi. To examine, accept, or reject everything, cGMP
vii. To guarantee that nonconformance is looked into
viii. To report information to management.
ix. To continue being independent. [1, 21]

Total Quality Management -

TQM is considered a customer-focused process that focuses on consistently improving business operations management. It strives to ensure that all associated employees work toward the common goals of improving product or service quality, as well as improving the procedures that are in place for production. [8]

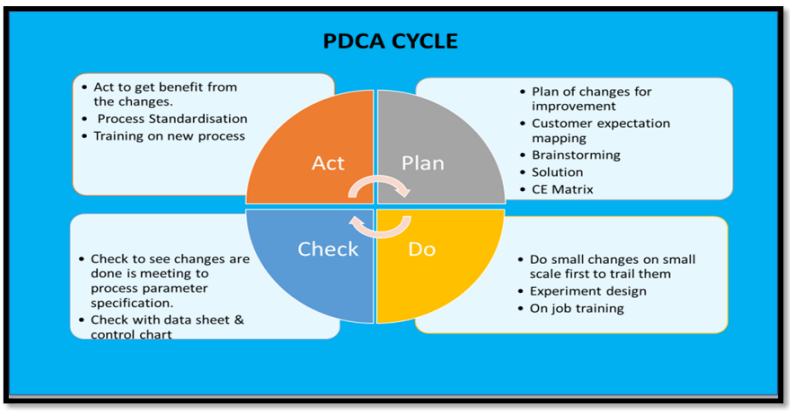

Figure No – 2 PDCA Cycle

The Basic Components Of Tqm -

1. Plan - plan for the new product development and production process.
2. Do - Put the procedures into action.
3. Check - Analyse the collected data to measure customer satisfaction.
4. Act -Continue to take steps to raise the standard of products [9]

Management of quality in different area of pharmaceutical

Various phases of TQM approach are described in figure: 3,

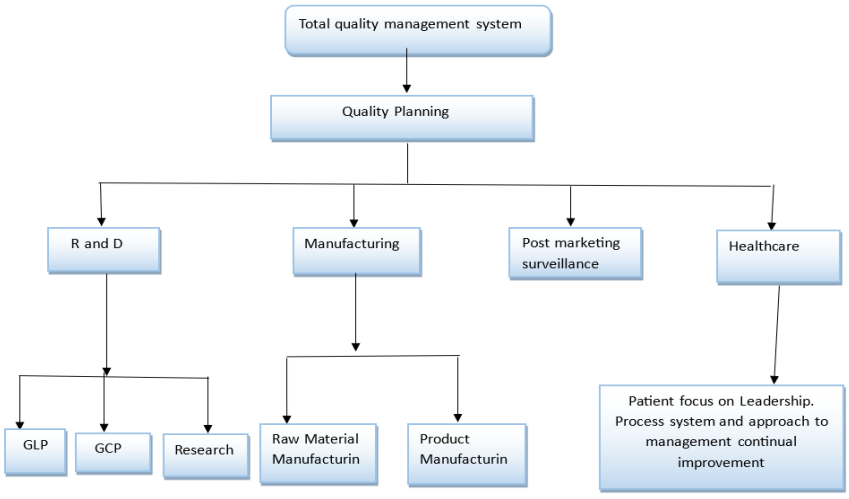

Figure No – 3 Various approaches in pharmaceutical industry

Quality planning -

The role of quality planning is to design a process that will be able to meet established goals under operating conditions. Quality planning is a methodology which can be used when a situation exhibits one or more of the following characteristics:

- A service has never existed before.
- Customer requirements are not known
- The existing service/process performance is not capable of meeting customer requirements

- The service/process is ad hoc; extremely variable; never been well defined or worked on before as a whole
- The environment is unstable, characterized by major market, technology or organizational change
- Performance data does not exist or it would require excessive time/expense to collect data. (10)

Research and development:

TQM is extremely important to the quality management of this process. It entails doing the following

- **GLP (Good Laboratory Practices) -**

1. It tightly regulates the use of animals in research experiments.
2. TQM in GLP includes the things listed below.
3. Creates the study's master schedule or procedure.
4. Keep a copy of the protocol, which is necessary to carry out research in a lab.
5. A regular examination of the tools used to conduct the study.
6. Documentation: If the study's approved protocol is changed, documentation of the modification and the rationale for it must be included. (11,12)

- **GCP (good clinical practices) -**

It tightly regulates the use of human subjects in clinical research. The GCP approaches are nearly complete. comparable to GLP's. The primary distinction is that prior to adding any subjects or people to the clinical trials program. To ensure that individuals are informed about the clinical trials study, a fully completed, signed informed consent form should be obtained from them. Documentation of these records is necessary If a patient protests during the study, the quantity protested and the cause for the protest should be recorded. (13 ,14)

Manufacturing:

In production, it includes manufacturing of both raw materials and API, production and packaging of dosage form, along with pilot plant scale up activities. (15)

Post-marketing surveillance –

Quality management is predicated on market research, which is predicated on post-marketing surveillance and entails modification. control, as well as its documentation, in the event that the authorized procedure needs to be changed. (16)

Healthcare:

The following are some of the aspects of quality management in healthcare: Patient-centeredness: healthcare organizations should prioritize meeting the needs of their patients and strive to go above and beyond their expectations. (17)

- **Leadership:**

The organization's direction is set by its leaders. It establishes and preserves the internal atmosphere necessary for individuals to completely accomplish the goals of the company. (18)

- **Process and system approach to management:**

When tasks are handled as a process, a desired outcome is attained more quickly. recognizing, comprehending, and overseeing the system to successfully archive the organization's goal.(19)

- **Continuous Improvement:**

Improving the organization's overall performance should be a constant goal.

ICH Q10

The ICH Q10 model is accepted in the US, Japan, and the EU; it is not required but is advised. The ICH Q7 guideline, published by the International Organization for regional requirements for good manufacturing practices and ISO QMS standards. Quality expectations can be raised with the help of an efficient QMS implementation using the ICH Q10 paradigm. Innovation must be used continuously to improve ICH Q10 implementation throughout the product lifecycle. This may bolster the claim that manufacturing operations as well as

drug development. The organization's quality is shown in its ICH Q10 compliance. [1,22,23]

Goal of ICH

The primary goals of ICH are to:

a) Keep track of, update, and expand the worldwide synchronization of the technical specifications.

b) To guarantee the efficacy, safety, and quality of medications that need to be created and approved in the most economical and efficient way possible.

c) To advance and safeguard public health from a global standpoint.

d) To avoid needless repetition of human clinical trial conduct.

e) To reduce animal testing as much as possible without sacrificing efficacy or safety.

f) To increase the worldwide drug development process' effectiveness.

Need of ICH –

The guidelines assisted in bringing about global product quality harmonization for the export of medications without any disruption at the global level

ICH 10 Pillars –

Process performance and product quality monitoring system

a. To maintain a state of control, pharmaceutical businesses need to design and implement a system to track both process performance and product quality. A management approach that promotes Quality risk management can be used to create CAPA that is effective.

b. Audits, which provide ongoing observation and tracking of the quality system, might be a QMS solution. It provides a quality benchmarking approach for different product lines and workflows. Any flaws in the system can be found through GMP audits. Additionally, it simplifies a number of processes to determine the system's compliance efficiency. [5]

System of Corrective and Preventive Action

The non-compliant events can be corrected by corrective actions, and risk management guidelines can be used to gauge such activities.

Change Management System

Management Review Of process performance and product quality

Application of these Q10 pillars along with additional tools by pharmaceutical companies support in effective QMS implementation.

Audit –

Via the company's QMS, regular audits of various operating areas and departments can be planned. Corrective action might be connected to the audit results to ascertain the organization's current compliance status and opportunities for development. (5, 20)

Corresponding QMS solution –

recording adverse events and managing complaints Another component of the process performance and product quality monitoring system is gathering input from both internal and external sources. The QMS's complaint handling feature, which This input can be obtained by using a system that handles complaints in accordance with FDA regulations.

During this function, post-market feedback related to the examination of unfavourable events is recorded. It can be electronically sent to the US FDA or directly linked to the CAPA, where the adverse event data can be carried over into corrective action.

Corresponding QMS solution for products that do not comply –

The products pass safety regulations and are approved based on testing that verifies conformity to the specifications. The tracking, observation, evaluation, and disposal of non-conforming products are made possible by Q10's non-conformance capability. To address systemic problems, the original non-conformance can directly lead to the creation of a corrective action. It guarantees the optimization of the non-

conformance process and improves the safety of the final product.

CAPA system -

In accordance with ICH Q10, a CAPA system is required for audits, non-conformance, product rejection, and complaints. It is possible to look into occurrences and identify their underlying causes. using the CAPA system.

The CAPAC system can be used for both corrective action and the verification of successful activities.

Corresponding QMS solution - risk assessment

By using the risk assessment feature, the quantity of CAPAs can be decreased. It assists in separating important events from less important ones that affect the organization.

The risk assessment event includes risk mitigation tracking, which makes ensuring that risks are reduced by taking preventive and remedial measures.

Using the continuous improvement approach, organizations can create risk portfolios for individual goods. Through the use of a risk portfolio, past adverse event history as well as the risk ranking associated with each event may be observed. Pharmaceutical companies can reduce or eliminate unfavourable events by using the prior risk assessment portfolios as a guide.

Change Management System-

Product lifecycle modifications are necessary for ongoing product improvement. Every business needs a change management system in order to properly assess, approve, and monitor changes, as per ICH Q10.

QMS solution Change Management –

A pharmaceutical company can initiate the change process by putting the change management feature into place. A non-conformance, a corrective action, post-market feedback, an audit, or other comparable quality issue may have led to the adjustment. One can take quality data and apply it to a change management project plan.

Management review-

Management reviews ensure the effectively management of process performance and product quality throughout the lifecycle. It also imparts assurance that the quality and compliance is completely met by the organization. Management reviews is a medium through which senior management can be aware about the quality concerns on timely basis.

Corresponding QMS solution - Reporting system

The QMS contains a vast amount of data on audits, adverse events, non-conformance, corrective measures, etc. In the absence of ongoing improvement, there may be gaps in a transparent way to assess the data. It may cause management's ability to make decisions to be delayed. The reporting system feature helps the company make wise decisions to manufacture high-quality, safe products by helping it better grasp quality difficulties. It can help with data analysis, summarization, result comparison, problem isolation, and progress tracking.

Automated mechanisms – Automated QMS solutions can achieve a number of hereditary benefits, such the most efficient process simplification. Among the main advantages are.

Scalability-

No pharmaceutical company is restricted to a single location. There are numerous sites with varied facilities. Processes that can satisfy the requirements of every facility must be distributed by an efficient QMS via a shared platform accessible from the corporate office.

Flexibility:

The system needs to be able to change to accommodate various business procedures. Using an automated QMS system can let you improvise and change seamlessly. Several departments, operational areas, and particular business processes can all perform effectively under the

QMS with the help of a centralized administration feature. [5,20]

CONCLUSION

The pharmaceutical sector must develop quality management systems in order to provide a quality, safe, and product with no defects at a reasonable price There is no single definition of the word "quality." It is tensile in nature, and while different people have different definitions of it, all of them have satisfaction in common. If the product fulfils the manufacturer's specifications and the customer is Satisfied when the specific product meets his needs. However, quality is an essential component of modern life and cannot be disregarded. In the pharmaceutical industry, quality is a legal concern that needs to be upheld in pharmaceutical products. The current study focuses on a few areas and the necessity of using a quality management system to preserve quality in the pharmaceutical industry. The use of Q10 guidelines is one way to specifically achieve an effective pharmaceutical QMS. While it's not required, adopting ICH Q10 can help a pharmaceutical company comply to the law and keep improving.

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