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REVIEW ARTICLE

Review on "Positive Influence" of Quality Management System in Pharmaceutical Industries

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ABSTRACT

The "Quality policy" is designed and implemented by the management function known as the pharmaceutical quality management system. In recent year, the pharmaceutical manufacturing sectors have just started to implement the US Food and Drug Administration (USFDA) requirements. The effectiveness of the QMS directly affects the company's capacity for sustainable growth and competitiveness. A long-lasting, trustworthy relationship with customers can be maintained with the certification of a quality management. The most crucial objective of the pharmaceutical sector is the implementation of an adequate quality assurance policies and Quality Management System. Total Quality Management (TQM) play vital role in accomplished the goal. It regulates the complete quality system chain of a pharmaceutical product, which the general people will buy and use when they are in need. For a quality improvement programme to be successful. They should always work to improve their company and production procedures in an effort to achieve excellence.

Keywords: *Quality Management System (QMS), International Conference on Harmonization (ICH), Total Quality Management (TQM), Quality Risk Management*

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INTRODUCTION

Quality management system is system which governs or directs an organization in term of quality or it is defined as an organizational effort to designed to enhance the quality at every aspect. Pharmaceutical industries are highly concern about the product quality and product design because slight mistake leads various consequences to the patients and sometime its leads to withdrawal of the drug from the market [1]. The pharmaceutical industries are most standardized manufacturing unit and quality management system play a vital role in the ultimate quality of the products. The Quality management system is covering all the documents and policies and standard procedures for the development of quality product. [2] The QMS is fully accomplish all current standards and guidelines which helps to advancement of the quality of the product as well as the it motivates each organization to produce and maintain the good quality of the product at every aspect and minimize the chances of errors [3,4,5]. In pharmaceutical industry, quality becomes an assure things. According to one definition, quality management is the part of management that decides and puts into reality the "quality policy," or the general aim and course of an organisation with regard to quality, as explicitly articulated and sanctioned by top management [6.7,8].

HISTORICAL OVERVIEW OF QMS

Over the last 60 to 70 years, the idea of a quality management system has become mandatory. early in the 1940s. Second quality changed after World War II to become more statistical in character. Static sampling methods were employed to assess quality, and a quality control chart was used to keep track of the manufacturing process. With the aid of so-called quality gurus, the idea gained wider significance in the 1960s. Quality started to be seen as a concept that applied to the entire business, not just the production process. Quality was viewed as a concept that affected the entire business because all functions shared the costs of poor quality and were accountable for the product quality. Since the middle of the 1980s, total

quality management has been regarded as the panacea for a variety of organizational issues, including poor organizational performance. Successful businesses today recognize that quality offers a competitive advantage [1].

ICH

Stands for “International Conference on Harmonization” of technical requirements for registration of pharmaceutical for human use. International Conference on Harmonization is a joint drive comprehend both Regulators and Exploration based industry action of the Europe, Japan and US for the experimental and scientific conversation of the testing method required to determine and establish the Safety, Quality and Efficacy of the medication. The Quality Management System is used to preserve product quality in the pharmaceutical industry. international agreement on the advice the idea of the present pharmaceutical quality management system is governed by ICH Q10, which is in its last stages of implementation for the USFDA and Registration of Pharmaceuticals for Human Use .[7,8]

ICH Q10

The International Organization for Standardization's (ISO) ICH Q10 presents one detailed concept for an efficient pharmaceutical quality system (ISO). Good manufacturing practise (GMP) rules are included as well as quality ideas that support them. The ICH Q10 should be used to strengthen the relationship+ between pharmaceutical development and manufacturing activities, promote innovation, and promote continuous improvement throughout the product
lifecycle. [9,10,11]

NEED OF ICH

The guidelines made it possible to achieve global product quality harmonisation for uninterrupted global pharmaceutical export.

Quality metrics and Q – KPI (key performance indicators):

The USFDA coined the phrase "Quality Metrics" with the intention of creating rigorous inspection methods. It is primarily concerned with the oversight of the quality control process, which is connected to ongoing improvement. Key performance indicators for quality (KPIs) assist in monitoring and sustaining high levels of health. [12]

The following are some areas where the USFDA makes use of quality metrics data:

- To set up an indicator programme to pinpoint the goods that could pose a serious risk to consumers.
- To identify the circumstances where the medicine supply may be disrupted.
- To conduct thorough inspections of businesses.
- To enhance FDA's monitoring of pharmaceutical producers.
- The FDA evaluates the following pharmaceutical quality criteria based on information about industrial performance.
- Lot Acceptance Rate (LAR), a metric for gauging the efficiency of the manufacturing

process [12,13, 14].

QUALITY

Though frequently employed, the word "quality" can also be construed incorrectly. The concept of quality is unusually fluid; it is simple to picture yet challenging to express. It is a question of feeling, and based on the described perspective, the meaning differs from person to person. Quality is described in a variety of ways by quality gurus, including: adherence to standards or specifications; fitness for use; capacity to satisfy customer demands or expectations; etc. According to code, "quality" is "the whole of a product's or service's features that are consistent with its capacity to satisfy the needs specified. "To compare the various brands of that tablet's efficient therapeutic efficacy while choosing which one to buy. Although the term "quality" is frequently used and appears to be quite simple, it might be challenging to define accurately. [15] The pharmaceutical industry is the most important part of our health care system and direct deals with the human welfare in terms of medicines and medical devices so the quality of the product is very important at every aspect because all the pharmaceutical product are directly deals with the life of patients. After conducting testing, it was determined whether the product was of the desired quality or not. If all of the final product's parameters were found to be within acceptable limits, it was regarded as a high-quality product; however, if findings were found to be outside of acceptable limits, the product was deemed to be of low quality and was rejected. The primary flaw with conventional approaches was the absence of any procedures or processes for managing the quality of the final products.[16] We shall compare the many brands of that tablet when choosing which one to buy based on its medicinal efficacy, side effects, colour, and aroma. In order to compare the quality of the product, the buyer or user compares its features or qualities with those that it lacks. make the word's correct meaning clear. The first has to do with the qualities and characteristics of the good or service. This guarantees that

the goods or services satisfy the user's requirements. The second factor relates to the product's lack of flaws. Quality is a word that is frequently used but also open to misunderstanding. Despite being challenging to define, quality is an
unusually fluid term. [17,18]

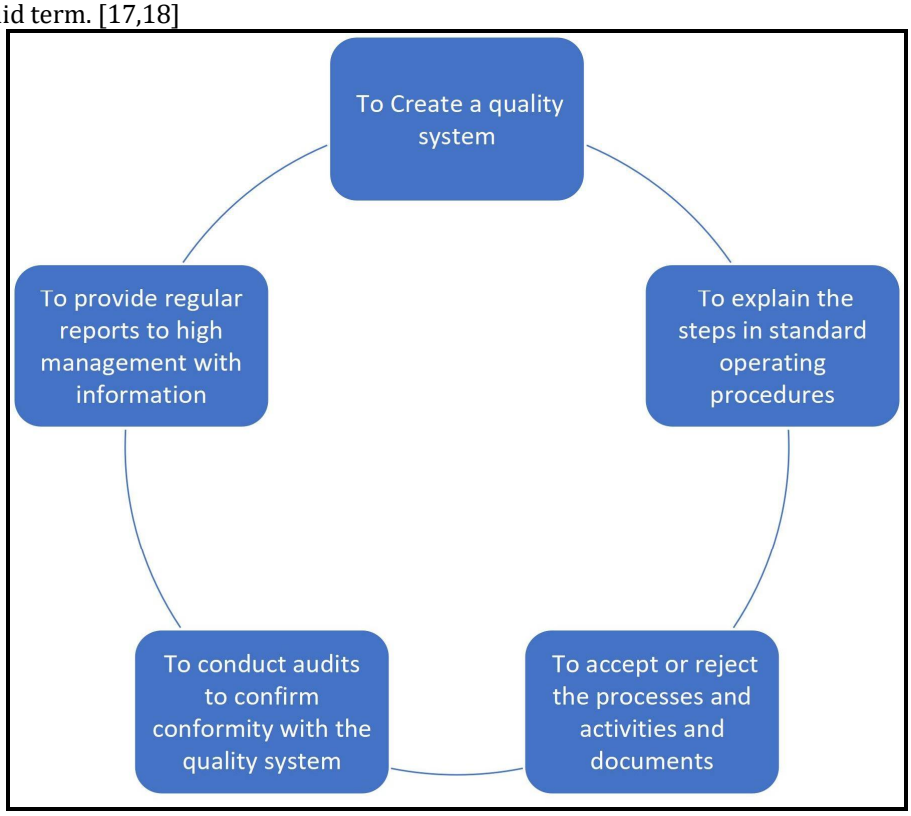

Fig:-1 Duties of a pharmaceutical quality unit

Essential Qualitative Management System Principles

To attain the goal of producing high-quality, safe products, every business must implement a quality management system and protocols. This system operates under the following
principles i.e.[19]

- Quality management
- Total quality management
- Six Sigma
- Change Management/ Change control,
- Out of Specifications (OOS)
- Out of Trend (OOT)
- Corrective & Preventive Actions (CAPA)
- Deviations

THE BASIC COMPONENTS OF QUALITY MANAGEMENT SYSTEM INCUDES

•Organizational structure procedures, processes and the resources are covered in quality management system.

•A suitable "quality system" or infrastructure that includes the organizational structure, policies, practices, and resources.

•The systematic steps to guarantee that a product (Service) will meet the specified standards for quality the entirety is referred to as "quality assurance. [20,21]

ELEMENTS OF QUALITY MANAGEMENT SYSTEM

A quality management system typically has four parts:

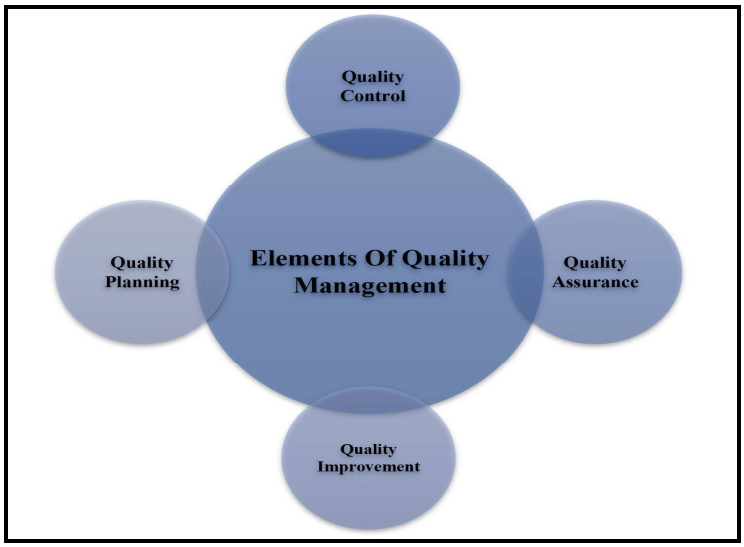

Fig.2- Element of Quality Management

QUALITY PLANNING

The approach for incorporating business policy into practices, guidelines, and instructions to obtain measurable goals and demands.

QUALITY ASSURANCE

To ensure that products are manufactured in accordance with quality standards, plan the activities and implement them as a component of the quality system.

QUALITY CONTROL

The process of observing and correcting to guarantee the creation of high-quality products. ensuring that quality standards are fulfilled by the monitoring, evaluation, and adjustment of a process, product, or services.

QUALITY IMPROVEMENT

The procedure used to monitor and make corrections to ensure the creation of high-quality items. [23,24]

Management responsibility

Establishing and upholding company-wide commitment to quality is crucial for the effectiveness of the pharmaceutical quality system. According to the quality policy, management is responsible for achieving quality-related targets. All levels, including individual and group roles, must have a clear grasp of and unambiguous set of authority and duty. It is necessary to show a strict dedication to the quality objectives.

Management should:

- Join in on the planning, execution, supervision, and upkeep of successful pharmaceutical quality system.
- Support the pharmaceutical quality system strongly and openly, and see to it that it is applied throughout the company.
- Make sure there is a timely and efficient escalation process in place to bring quality issues up to the proper levels of management.
- Define the duties, responsibilities, powers, and interrelate
- Townships of each organisational unit in respect to the pharmaceutical quality system, both individually and collectively. Make sure that everyone in the organisation is aware of and understands these interactions. Regional regulations call for an autonomous quality unit or structure with the power to carry out certain pharmaceutical quality system duties.
- Organize management reviews of the pharmaceutical quality system, process performance, product quality, and product quality [25].

Benefits of QMS

- Enhanced goods and/or service quality.
- Reduced incidence, rejection, and complaint rates.
- lower internal costs.

- a higher profit margin.
- Improved employee retention and motivations.
- Employees are more knowledgeable about quality.
- Process and procedure improvements.
- improved client satisfaction.
- Greater advantage over competitors.
- established brand recognition in the marketplaces. [26]

Total quality management system (TQM)

TQM is an innovative concept for quality control. It is a novel approach for achieving good quality in all aspects it is basically concerned about the customer quality satisfaction. TQM is high quality management system focus on the customer need, employee involvement and focusing on continuous improvement of quality. TQM is collectively attempted to design by the organization for enhancing the quality of the product. TQM is also known as costumer defined quality TQM helps to the organization to take the decision in a logistic manner in the favour of the company. The focus of TQM is to get the product quality not at local as well as global market. [27] The International Organization for Standardization (ISO) describes TQM as "a management approach for an organisation, focusing on quality, based on the participation of all members of the organisation and society as a whole will benefit, and long-term success will be achieved via customer happiness. TQM is referred to as "a management approach for an organisation, focussed on quality, based on the engagement of all its members and aiming at long-term success through customer satisfaction and benefits to all members" in ISO 8402:1994. Although quality assurance staff are in charge of assuring product quality, several departments and disciplines at all levels must assume accountability and guarantee quality. Quality must be achieved at every level, and this demands teamwork from everyone, not just the top management. [28]

The benefits of TQM are:

1. Identify the problems and errors and resolve them quickly.
2. Comparatively low at cost.
3. Minimize the wastage of the product as its quality is altered before.

Pharmaceutical quality deviation:

The challenge of quality improvement was shared by all, and the department of quality control and quality assurance only lately entered the scene.

Failure is the state or condition of falling short of a desired or predetermined standard and is seen as the opposite of compliance.

Deviation Classification

Personnel must fully understand how to handle deviations in accordance with GMP criteria as a fundamental component of the deviation management process. Personnel should also be informed of any modifications in the present procedures. Following are the categories for the deviations:

Small Deviations;

A deviation can be treated as slight and in line with applicable regulations if it has no impact on a quality attribute, a crucial process parameter, or any instrument.

Large deviations;

If a deviation affects any quality characteristics, a crucial process parameter, a piece of equipment, crucial for process control and can be regarded as a significant deviation.

Critical deviations;

A deviation is deemed important if it has an adverse influence on any quality characteristics, a crucial process parameter, a crucial piece of equipment for process control, as well as the patients and customers, especially in cases where their lives are in danger. [29]

Quality risk management

It is a methodical process of determining, managing, communicating, and reviewing the risk of product (medical) quality throughout the course of the product life cycle. A number of features, such as risk identification, data analysis, risk planning, risk monitoring, and risk management, are included in QRM. [30,31].

FIG.3- COMPONENTS OF QUALITY RISK MANAGEMENT

CONCLUSION

The implementation of the QSM is requires in ever safety aspect drugs and chemicals is a big concern for everyone, as well as a major objective in the workplace and in daily life. To maintain compliance with regulations and to ensure the cost-effectively ensuring product supply continuity, and process need to be assessed and managed. Accurate and high-quality tools are crucial in this situation. Key Performance Indicators (KPIs), metrics, improving the quality of final products. Since many years ago, the pharmaceutical sector has mostly employed the Quality management system (QMS) to assess operational performance. However, there are numerous methods and stages at which quality can be assessed.
Companies can achieve high-quality performance if quality metrics are applied correctly.

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CONFLICT OF INTEREST

No conflict of interest

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