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REVIEW PAPER

Role of Total Quality Management in Pharmaceutical Industry

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ABSTRACT

Total Quality Management (TQM) is a concept which is known for the improvement of the quality, productivity, business operations, quality culture. Essential requirements for the successful implementation are commitment, continuous improvement, culture, control and customers focus. The main aim of Total Quality Management (TQM) is to provide improved quality of product and service to customer. Indian Pharmaceutical Industry started isolation and purification of compounds in the modern era of 19th century. After 20th century, pharmaceutical industry stared facing different challenges while control and elimination of disease was because of advancement in pharmaceutical industries. Total Quality Management (TQM) is required in pharmaceutical industry for maintaining quality and purity of drug. Quality of the product is necessary to meet the expectation of the customer. There are eight dimensions of quality; performance, reliability, durability, aesthetics, features, conformance, serviceability and perceived quality which are the main ingredients to success. Total Quality Management (TQM) helps in increasing business and reducing losses due to wasteful practices in pharmaceutical industries. It is applied in various branches of pharmaceutical industry such as research and development, manufacturing and post marketing surveillance. Different approaches are involved in Total Quality Management and some of the recent technological advancements are supporting Total Quality Management (TQM).

Keywords: - *Knowledge, Pharmaceutical bioinformatics, Attitude, Software, Practice, Drug discovery, Medical practitioners.*

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INTRODUCTION

During Total Quality Management (TQM) is a customer oriented process and aims for continuous improvement of business operations. All allied works are ensured to be towards the common goal of improving service quality or product quality. It also enhances the production process and process of rendering of services. This also helps to increase the awareness of the quality culture within the organization and special emphasis on team work will be achieved. It will lead to a commitment towards continuous improvement. The key principles of total quality management are, commitment from the management, employee empowerment, continuous improvement and customer focus.[4]

TQM is now recognized as a generic management tool, just as applicable in service sector organizations. The concepts of quality control and quality assurance follows and develops standard operating procedures (SOP) directed towards assuring the quality, efficacy and safety. A fundamental regulation is issued by world health organization (WHO) to pharmaceutical industries entitled good manufacturing practice (GMP) for pharmaceuticals. Many countries have formulated their own requirements for GMP, based on WHO GMP. The drug product must be safe effective and must meet certain criteria for quality and purity. Quality is a critically important ingredient to organizational success today. This can be achieved by Total Quality Management (TQM) which is an organization wide approach that focuses on quality as an overarching goal. The organizational unit must work harmoniously to satisfy the costumer, is the basis to this approach. The organization must strive to continuously improve its system and practices because the customer's needs are always in constant flux. TQM views quality as the central purpose of the organization and in contrast to the focus on efficiency advocated by the operational perspective. [8]

Total Quality Management (TQM) includes both direct and indirect employees in quality culture of companies. It does not only include Quality Assurance (QA) and Quality Control (QC) departments but all the departments in the industries. Functions such as research and development (R&D) and supplier management along with manufacturing are also affected by TQM. The objective of TQM is improving quality of products and process while maintaining overall quality of industry. **Process management, customer involvement, cross-functional product development** and **supplier quality management** are the elements of Total Quality Management (TQM). [1]

Essential requirements for successful implementation of TQM

1. **Commitment:** In the organization, quality improvement is everyone's job. Different aspects such as breaking down the barriers for continuous quality improvement, an apparent commitment from the top management and steps required to provide an environment for changing attitudes.
2. **Continuous improvement:** Recognize improvement as a continuous process, not merely a one-off program.
3. **Culture:** To effect the changes in attitude and culture there should be proper training.
4. **Control:** For any deviation from the intended course of implementation, monitoring and control checks must be ensured.
5. **Customer focus:** Full satisfaction and perfection in services with zero defectives to end-users whether it's internal or external. [4]

The universal Total Quality Management beliefs are everyone is an owner, analysis of the processes is the key to quality improvement, it is important to incessantly improve quality of the products and

services which we are supposed to provide to our customers, satisfaction of the customer is the measure of quality, analysis of the processes is the key to quality improvement and constant TQM is not possible without consistent, active and services which we are supposed to provide to our customers. [4]

ADVANTAGES OF TOTAL QUALITY MANAGEMENT

1. It is quality control inspector.
2. Higher employee morale- workers are motivated by team work, extra responsibility and involvement indecisions of TQM.
3. Lower cost- it decreases waste as fewer defective products and hence there is no need of separate.
4. Improves reputations- problems and faults are sorted and spotted quicker. [5]

DISADVANTAGES OF TOTAL QUALITY MANAGEMENT

1. Workers may be resistant to any change.
2. Cost of initial introduction.
3. For several years benefits may not be seen. [5]

INDIAN PHARMACEUTICAL INDUSTRY

In 19th century the modern era of pharmaceutical industry started with isolation and purification of compounds, computer aided drug design and chemical synthesis. After intuition and trial and error for thousands of years, humans started to believe that animals, plants and minerals contained medicinal properties. Research in the fields of physiology and chemistry in 20th century increased the understanding of basic drug discoveries. The different challenges faced by pharmaceutical industry are identifying new drug targets, attaining regulatory approval from government agencies, and refining techniques in drug discoveries and development. Control and elimination of disease around the world is because of continues evolution and advancement of pharmaceutical industry. To maintain quality and purity of drugs in pharmaceutical industry total quality management is required. [7]

In terms of volume, India's pharmaceutical industry is now third largest in the world. In terms of value its rank is 14th. The total turnover of India's pharmaceutical industry between September 2008 and 2009 was US$ 21.04 billion. This was reported by Ministry of Chemicals and Fertilizers, also by Department of Pharmaceuticals. One of the strategies that differentiate company from its competitors is quality. Pharmaceutical industry is heavily regulated apart from safety and mistake in any product design or production can have severe or fatal consequence for patients. Pharmaceutical companies build their quality approach around Good manufacturing practices, Good clinical practices, Good laboratory practices and In-house standard operating procedures. [8]

In pharmaceutical industry, there is great scope of improvement in production rate as it one of the promising industry of India and will help the economy to grow. Adequate functioning of equipments and machines are the necessary for production and quality. Efficient production system leads to continuous need of production via adoption of total productive maintenance (TPM). The requirement of market changes very fast and TPM helps industries to meet the need. In last three decades of the century, TPM has been evolved. [2]

CHALLENGES IN FRONT OF PHARMACEUTICAL INDUSTRY

A change in pharmaceutical industry has taken place in recent years and is likely to continue in future and hence it is in an increasingly dynamic and complex environment. Levels of uncertainty is increased due to global competition, opening of markets and technological advancements. Loyalty to major branded drugs is threatened due to the emergence of generic drug, which is one of the major change in the pharmaceutical industry. When a patent expires of a product, generic drug is made from that product ate cheaper price. Technological new product success is rested due to growth of many organizations. Example, on the back of Zantac, Glaxo has enjoyed huge success. For a new drug to develop it would take 10 to 12 years but due to chemical and computer advances it has became easy for competitors to develop such drugs in 18 months. Smaller companies are trying to make inroads into the market as the customer demand changes and barriers come down. They are trying to adapt changing market conditions and are competing on innovation and flexibility. Companies brought medications to market that are safe and effective. And now the consumers have became more educated, aware and demanding. Pharmaceutical companies are now forced to change the way they used to do business as there is increase in power of customer. The last is the requirement of new approaches as the clinical development will be done remotely and electrically. Some of the skills which are required by clinical development professionals are technical therapeutic skills, highly developed communication skills, IT competency and commercial abilities. Pharmaceutical industry will need to embrace an entrepreneurial approach and move beyond its conservative look to embrace new ideas and skills for the development. [9]

QUALITY

Quality can also be described as very vaguely. It is a slippery concept easy to visualize and difficult to define. Quality is defined in different ways by such as conformance to standards and specifications, fitness for use, delighting the customer, meeting customer's requirements or expectations, etc. While purchasing tablets, comparison between different brands is made on the basis of therapeutic efficacy, side-effects, colour and odours. Thus making comparison of features and attributes of product also checking for absence of deficiency, this all is done while comparing the quality. The quality has two

aspects, one relates to features and attributes of the product or services while other concerns the absence of deficiencies in the product. [3]

The eight dimensions of quality which are important ingredients to organizational success, are:

1. PERFORMANCE: Primary operating characteristics of product.
2. RELIABILITY: During a specified time there should be no malfunctioning.
3. DURABILITY: Product life measurement.
4. AESTHETICS: How a product tastes, smells, looks and feel.
5. FEATURES: Supplements to product's basic functional characteristics.
6. CONFERMANCE: The degree of meeting of established standards and, product's design and operating characteristics.
7. SERVICEABILITY: The ease and speed of repair.
8. PERCEIVED QUALITY: The way customers see it. [3]

THE KEY ELEMENTS OF TQM APPROACH ARE

1. Focus on the customer: Identifying the organization's customers is very important. The organization's product and services are consumed by external customers and internal customers are employees who receive outputs of other employees.
2. Employee Involvement: Since quality is most preferred, job of all the employees should be involved in quality initiatives. The closest contact with external customers is of frontline employees and hence can make the most valuable contribution to quality. Employees are authorized to innovate and improve quality.
3. Continuous Improvement: People are working continuously in this never-ending process of quality quest to improve the performance, speed and number of features of the product and services. Small, incremental improvement that is continuous improvement which occurs on a regular basis will eventually add up to vast improvement in quality. [3]

IMPLEMENTATION OF TQM IN PHARMACEUTICALS

Whether it may be pharmaceuticals, medical devices, biotech or host of other life sciences manufacturer, it is difficult to achieve and maintain Total Quality Management, be it a company striving to maintain high levels of quality for its own sake or with ISO, FDA, EMEA Regulations. Without considerable organizational and human resources, TQM cannot be achieved. It is a method by which employees and management can become involved in continuous improvement process of production of goods and services. It is aimed at increasing business and reducing losses due to wasteful practices. Total Quality is description of attitude, culture and organization of a company strives to provide customers with services and products that satisfy their needs. [8]

TQM is a collection of processes and it maintains that organizations must strive to continuously improve processes by incorporating experiences and knowledge of workers. It is infinitely variable and adaptable. Different sectors are creating their own versions from the common ancestor with number of evolutionary strands. Total Quality Management is the foundation for activities that includes;

1. Commitment by all employees and senior management.
2. Meeting requirements of customer.
3. Reducing time of development cycle.
4. Reducing costs of product and services.
5. To facilitate improvement by different systems.
6. Celebration and recognition.
7. Quantified goals and benchmarking is challenged.
8. Focusing on processes and improvement plans. [8]

MULTIFACETED APPROACH

Total Quality Management is a multifaceted approach for quality management among various different branches of pharmaceutical industry. They are as follows;

1. **Research and development:** In the quality management of research and development, TQM plays a very vital role. In Good Laboratory Practices, there is strict control over use of animals in the laboratory for experiments. There must be preparation of protocol or master schedule sheet for the study. The copy of the protocol must be maintained in which study is to be carried out in the laboratory. There must be periodic inspection of facility in which study is to be carried out. There should be documentation and approval of the change, if any change is there in approved protocol with the reasons for carrying out the change.

   Good Clinical Practices involves strict control over use of human beings in clinical trials. If any human being is involved in clinical trials then there must be complete duly filled informed consent form which should be taken from subject along with their signature to make sure that they know about it. Records should be maintained. [6]
2. **Manufacturing:** In the production, along with production and packing of dosage form it also includes manufacturing of both raw materials and API.
3. **Post Marketing Surveillance:** Based on market survey, quality management is done. Which is based on market surveillance and also involves change control and documentation is required in approved process. [6]

APPROACHES FOR TOTAL QUALITY MANAGEMENT

1. **Six Sigma Technique:** Set of techniques or tools used for quality management or process improvement. This technique can improve the quality of process outputs by identifying and removing the causes of errors or defects and minimizing variability in business and manufacturing processes. The tow methods involved in this technique are;

   DMAIC (Define, Measure, Analyze, Improve, Control), which involves 5 phases used for improving existing business processes.

   DMADV (Define, Measure, Analyze, Design, Verify), also involves 5 phases used for creating new business processes or creating a new product.

2. **Lean manufacturing:** This term was first coined by John Krafcik in 1988. This technique does not include many tools and hence includes reduction of three types of waste; MUDA-Non-value-adding work, MURI-Overburden and MURA-Unevenness. The main aim is to minimize the use of those resources, which do not add up value of final product which ultimately reduces cost and increases the quality. Word LEAN means putting the right things in right place so processes can go on smoothly without any problem.
3. **Quality Risk Management (QRM):** QRM is defined as method for assessment, communication, control and review of risks to quality of medicinal (drug) product through product lifecycle where decisions can occur at any point. It is widely used in pharmaceutical industry that involves systemic procedures for identification, analysis and control for risk which are involved in any ongoing processes. It also includes identification of risks, analysis of data, planning, track, control and communication.
4. **ISO Series:** In 1987, ISO 9000 series of standards developed by International organization for Standardization. It was developed to maintain an effective system for quality management and quality assurance of manufacturing industries. Quality management system is influenced by its varying needs, its business environment, its particular objectives, changes in environment, the product it provides, its size and organizational structure, and the processes it employs.
5. **Current Good Manufacturing Practices (cGMP)**: It is a quality management technique of pharmaceuticals. Various agencies such as US FDA, WHO, European medicines agency schedule M in India have given guideline for good manufacturing practices. Different types of guideline includes facilities, disposal system, testing, recording any reprocessing or recall, filling of change controls if any change in process, clothing, sanitation, and recording of analysis. To ensure good quality in the product, it is necessary to have thorough knowledge about good manufacturing practices. [6]

RECENT TECHNOLOGICAL ADAVNCEMENTS SUPPORTING TQM

Automated approaches for real time quality management of pharmaceuticals

To maintain quality at different stages of a process, automated approaches are used. This helps to decrease requirement of sampling and testing at various stages as these analyzers and probes give automatic reading for operation. Few of them are;

1. **Diffuse reflectance measurement:** For powdered or crystalline material, it is an excellent sampling tool in mid-IR and NIR spectral ranges. It is used for monitoring an ongoing reaction or ongoing processes.
2. **Sensors based technology in packing:** This technique has opened a new vista in online and in-process monitoring of packing process in packaging of pharmaceuticals. Some of the sensors are ultrasonic sensor for filling level measurement, fiber optic sensors for presence of product in packing, miniature background suppression sensor for content monitoring, and ultrasonic sensor for adhesive strip detection.
3. **CIP and WIP Probes:** Clean in probes (CIP) it involves cleaning of equipment with minimum involvement of the operator. WIP stands for wash in place. Some of their benefits are as follows; reduction of cleaning time, improved health and safety, procedures can be validated, saving of costs including chemicals, water and effluent, labour time, etc.
4. **Holographic techniques:** For consumers to analyze the authenticity of a drug, this technique provides a simplified means. By the help of interference patterns obtained through the interaction of laser beams, holograms are generated. Holograms which are currently available produce 2D-3D designs. In variety of formats such as holographic shrink sleeves, holographic induction cap seals and holographic hot stamping foil to identify the right product, holograms are available.
5. **Track and Trace authentication:** This software allows brand owners to manage their supply chain. Pharmaceutical industries are allowed to track their shipments from there to retail level, by encryption and decryption in the same way as courier companies track their shipments as they wind through shipping chain. [6]

CONCLUSION

Pharmaceutical industry is one of the leading industries in India. There are many challenges faced by the industry and it is necessary to maintain the leading position in the industries. The path of achieving quality certificate namely, ISO 9000 accreditation is followed by pharmaceutical industry. Certification is the step towards success and it helps in attracting customers. It also helps to show that an industry is progressing and growing. Total Quality Management (TQM) helps in achieving this quality certificate to a pharmaceutical industry. If there are no visible results, the enthusiasm can quickly fade for TQM. When key aspects of TQM are followed such as focus on the customer, supplier quality management and continues improvement, the organization has made progress.

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