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Total Quality Management in Industrial Pharmacy

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Abstract: *Total Quality Management (TQM) is a comprehensive management approach focused on improving the quality of products, services, and processes across all levels of an organization. Rooted in customer satisfaction and continuous improvement, TQM seeks to involve all employees in the pursuit of excellence. This management philosophy emphasizes strong leadership, teamwork, and a commitment to problem-solving, integrating quality principles into every aspect of operations. By fostering a culture of accountability and systematic processes, TQM aims to reduce waste, optimize efficiency, and enhance competitiveness. The ultimate goal is to create value for customers and stakeholders while building a sustainable, quality-driven organization.*

Keywords: Quality, Quality Risk management, ISO, GMPs, GCP.

I. INTRODUCTION

The pharmaceutical industries are vital segment of the health care system that conducts research, manufacturing and marketing of pharmaceuticals, biological products and medicinal devices used for the diagnosis as well as treatment of diseases [1].If products are not of appropriate quality then they could be result in severe adverse effects or even death of the consumers or patients. Initially concept of total quality control is used that quality is assured just on basis of quality control parameters[2]. But this concept of TQM involves building quality in a pharmaceutical product as it involve complete records such as standard operating procedures for every step, validation records, master formula records and batch production records etc[3]. This review includes information about quality, quality management, current status and need of TQM. This article describes TQM as multifaceted approach for quality management of pharmaceuticals by utilizing various quality management approaches such as quality by design, good manufacturing practices, quality risk management etc. leading to high quality products. An organizational infrastructure based on cross-functional teams is basic to NPRDC's TQM implementation model. Linda M. et.al., (February 1990),

Quality

Quality The term quality is used very commonly, this term looks to be very easy but it is difficult to define quality precisely

- As per ISO, it is defined as “Degree to which a set of inherent characteristics fulfills requirements”. Degree refers to a level to which a product or service satisfies. So, depending upon the level of satisfaction, a product may be termed as excellent, good or poor quality product. Inherent characteristic are those features that are a part of the product and are responsible to achieve satisfaction. Requirements refer to the needs of customer, needs of organization & those of other interested parties2.
- Quality has been defined in different ways by the quality gurus as conformance to standards or specifications; fitness for use; meeting customer’s requirements or expectations etc3
- Quality may also be defined as non-inferiority or superiority of a product
- Quality is a perception which may be understood differently by different people. The quality can be of two type

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Quality Management

Quality Management Quality management is management of various sectors to ensure good quality of the product. Quality management consist of four main components i.e. Quality planning, Quality control, Quality assurance, Quality improvement5.

Evolution of TQM

Evolution of TQM As in conventional systems, quality only depends upon final product quality control testing. They resulted in increase in cost and time consumption as detection of the problem is only possible at the end of the process. Scenario changed with change in evolution and application of TQM, i.e. every department is concerned with quality management of product. Quality is checked at every step in the process and if any problem arrives it is tried to be solved at that moment only. Quality does not depend only on final product quality control testing it is monitored in every step. So it also resulted in increase in quality of the product and also saves cost and time involved due to batch failure or due to solving a problem involved in the process. So TQM should be implemented by pharmaceutical industries as it result in increase in quality of the product, which is very necessary as pharmaceutical industry is most vital part of healthcare system and also decrease time involved in production, which ultimately result in decreasing cost of product.

Definitions

TQM is a combined effort designed by organization to improve quality at every level. TQM is about meeting quality expectations as defined by the customer; this is called customer-defined quality8. TQM consists of efforts of organization to install and make a climate in which an organization continuously improves its ability to deliver high-quality products and services to consumers. TQM efforts typically depend mainly on the previously developed techniques of quality control9. Various definitions of TQM given by global organizations are as follows: As per British Standards Institution standard BS 7850- 1:1992, TQM is a management philosophy and company practices that aim to harness the human and material resources of an organization in the most effective way to achieve the objectives of the organization10. As per International Organization for Standardization standard ISO 8402:1994, it is a management approach of an organization centered on quality, based on the participation of all its members and aiming at long term success through customer satisfaction and benefits to all members of the organization and society11. As per The American Society for Quality, this term was first used to describe a management approach to quality improvement. Simply, it is a management approach to long-term success through customer satisfaction. TQM is based on all members of an organization participating in improving processes, products, services and the culture in which they work9.
s'. It involves strict control over use of animals in the laboratory for experimentation. TQM in GLP involves following points: Preparation of protocol or master schedule sheet for the study,

REQUIREMENTS FOR IMPLEMENTATION OF TQM12, 13

1. Support from management
2. Employee Training and motivation
3. Thorough knowledge about cause and effects of the process TQM

A multifaceted approach TQM:

A multifaceted approach TQM is a multifaceted approach used for quality management among various branches of pharmaceutical industry i.e. research and development, production and marketing.
1. Research and development: TQM also plays very Research and development vital role in quality management of research and development process. It involves following points:
a. GLP: It is also called as 'Good Laboratory Practice GLP s'. It involves strict control over use of animals in the laboratory for experimentation. TQM in GLP involves following points:
• Preparation of protocol or master schedule sheet for the study,
• Maintenance of copy of protocol in the laboratory in which study is to be carried out,
• Periodic inspection of facility in which study is to be carried out,

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• If any change in approved protocol of the study then there should be documentation and approval of the change along with the reason for carrying out the change, and
• Documentation
b. GCP: It is also called as 'Good Clinical Practices' GCP . It involves strict control over use of human beings in clinical trials. The regulations for GCP are almost similar to that of GLP. The major difference being that before starting study or involving any subject or human being into the clinical trials. A complete duly filled informed consent form should be taken from subjects along with their signature to make sure that subject is known he/she is involved in clinical trials. These records should be maintained. If patient dropout involve during the study then number of dropouts along with reason of dropout from study should be documented.
2. Manufacturing: In production, which include Manufacturing: manufacturing of both raw materials and API, along with production and packaging of dosage form.
3. Post marketing surveillance: It also includes quali Post marketing surveillance: ty management based on market survey i.e. based on post marketing surveillance and involves change control and its documentation if any change is required in the approved process.

Quality by Design (QbD)
This concept was first given by Joseph M. Juran. He said that quality can be built in product by planning23. This technique is used for optimization of composition of ingredients of a formulation by use of statistical method. These statistical methods used for formulation optimization are approved by US FDA. ICH Q8 defines that pharmaceutical Quality by Design (QbD) is "a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management." Pharmaceutical QbD is a systematic, scientific, riskbased, approach to pharmaceutical development that begins with predefined objectives ICH Q8 defines design space from the concept that quality cannot be tested into product but has to be built in by designQbD approach requires thorough understanding of product and ongoing process i.e. complete knowledge about critical process parameters and critical quality attributes. It involves design of experiments, which involves identification of critical quality attributes and process parameters. It determines the relationship between critical quality attributes and process parameters in a design space. It designs a control strategy to produce the product consistently. It involves control over these parameters to achieve desired quality.

Quality Risk Management (QRM)
Quality risk management' is defined as a method for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product through the product lifecycle where decisions can occur at any point in the process. It is a widely used management tool used in pharmaceutical industry, which involves systematic procedure for identification, analysis and control of risk involved in any ongoing processs in the industry
Quality risk management includes:
• Identification of risks: It involves identification Identification of risks of risks before they become serious to be solved.
• Analysis of data: It involves analysis of risk data Analysis of data that and classifying the risks based on their impact and priority.
• Planning: Based on analysis of risk data planning f Planning or mitigation of risks involved and making decisions how to mitigate risks.
• Track: Monitor the plans for risk mitigation and al Track so monitoring risk indicators.
• Control: It involves strict control over risk Control mitigation plan to avoid deviation from these plans.
• Communication: It involves communication of Communication feedback about quality risk management plans.

ISO Series:
ISO Series ISO 9000 series is a series of standards developed by International organization for Standardization in 1987 to maintain an effective system for quality assurance and quality management of manufacturing industries27, 28. In this, ISO 9000 is concerned with the design and implementation of an organization's quality management system is

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influenced by: its business environment, changes in that environment, or risks associated with that environment; its varying needs; its particular objectives; the products it provides; the processes it employs; its size and organizational structure. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

Current Good Manufacturing Practices (cGMP)

This is also a technique of quality management of pharmaceuticals. Various agencies have given guidelines for good manufacturing practices such as US FDA, WHO, European medicines agency schedule M in India. These include guidance about choosing location, facilities, clothing, disposal system, sanitation, testing, recording of analysis, recording any reprocessing or recall, filing of change controls if any change in the process. So it is necessary to have thorough knowledge about good manufacturing practices involved in the process to ensure good quality in the product.

International Conference on Harmonization (ICH)

ICH has drafted guidelines for quality risk management of pharmaceutical products as Q9 guidelines and for pharmaceutical product development as Q8 (R2)22, 24. Q9 guidelines involve guidance about risk assessment, risk control and also give guidance about various methods for quality risk management such as failure mode and effect analysis (FMEA), failure mode, effects and criticality analysis (FMECA), hazard analysis and critical control points (HACCP), Preliminary Hazard Analysis (PHA), Risk ranking and filtering. So these various approaches such as six sigma, lean manufacturing, quality risk management, quality by design, ISO, cGMP, ICH etc. are used to for TQM of the process. The main tool of TQM is strong and proper system for documentation as any quality management system is incomplete without proper or complete documentation. Because it is common quote that 'anything that is not documented or recorded means not done'35. Therefore, for complete implementation of TQM, it is essential that everything should be properly documented in a good readable format that can be easily understood. Specifically if there is any change in the process or any deviation in the process than a proper change control or deviation control should be filed and approved for every change or deviation from the validated procedure

Key ICH Guidelines Relevant to TQM

ICH Q8: Pharmaceutical Development

- **Focus**: Emphasizes *Quality by Design (QbD)* principles, where quality is built into the product from the development stage.
- **TQM Principle**: Continuous improvement by understanding product and process parameters.

ICH Q9: Quality Risk Management

- **Focus**: Provides a framework for identifying, assessing, and managing risks to product quality.
- **TQM Principle**: Proactive risk management and decision-making to ensure quality consistency.

ICH Q10: Pharmaceutical Quality System

- **Focus**: Establishes a robust quality system for managing the lifecycle of a pharmaceutical product.
- **TQM Principle**: Integration of quality systems across the organization to enhance product quality and regulatory compliance.

ICH Q11: Development and Manufacture of Drug Substances

- **Focus**: Details the development and manufacture of active pharmaceutical ingredients (APIs).
- **TQM Principle**: Ensures that processes consistently produce APIs of the desired quality.

ICH Q12: Lifecycle Management

- **Focus**: Guides the management of post-approval changes to ensure quality across the product lifecycle.
- **TQM Principle**: Continuous improvement and adaptability throughout the product lifecycle.

ICH E6(R2): Good Clinical Practice (GCP)

- **Focus**: Establishes standards for the design, conduct, and reporting of clinical trials.
- **TQM Principle**: Ensures that the clinical development process adheres to quality and ethical standards.

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ICH M4: The Common Technical Document (CTD)

- **Focus**: Provides a standardized structure for regulatory submissions.
- **TQM Principle**: Streamlining documentation and communication for quality assurance.

Core TQM Components Supported by ICH Guidelines

- **Customer Focus**: Ensures the end product meets patient safety and efficacy needs.
- **Leadership Commitment**: Encourages top-level management involvement in quality initiatives.
- **Employee Involvement**: Promotes a culture of accountability and awareness among all employees.
- **Process Approach**: Highlights robust design, manufacturing, and distribution processes.
- **Continuous Improvement**: Encourages data-driven improvements and lifecycle management.
- **Data Integrity and Documentation**: Ensures traceability and compliance with regulatory standards.

Implementation Strategies

To apply TQM effectively using ICH guidelines:

- Integrate **ICH Q8-Q12** into the organizational quality management system.
- Train personnel on **ICH standards** and their role in achieving total quality.
- Use tools like **risk management frameworks** and **process analytical technology (PAT)** to align processes with TQM goals.
- Regularly audit and review processes against ICH and local regulatory standards.

Assumptions and Limitations:

It is possible that representatives answered more positively in order to achieve better results in the survey. As the survey was completed by representatives on management level, it could be the case that answers by them do not reflect the overall opinion of the employees of different hierarchical levels at the production site. For example, the elements of the sub-system EMS could be assessed more positively because it is completed by a manager as this does not represent the overall opinion of the workers. The analysis includes pharmaceutical and biotechnological production sites. Although both types of production processes include different sub-processes, e.g., biotechnological production includes purification

Total Quality Management:

A comparison between the performance indicators, assessing upstream quality (complaint rate supplier), internal process quality (rejected batches) and for downstream quality (complaint rate customer), in 2004 and 2009 is done. Furthermore, the implementation levels of factors such as “Process management”, “Cross-functional product development”, “Customer involvement”, and “Supplier quality management” are investigated (Fig. 4). Only six out of 1,000 customer orders delivered resulted in a complaint by the customer in 2009, compared with ten out of 1,000 in 2004. Rejected batches as a percentage of all batches produced, a core measure of the process quality, decreased from 1.00% in 2004 to 0.74% in 2009. More transparent scale-up processes and teamwork of R&D, manufacturing, and QC/QA departments mainly caused this result. Despite the fact that companies tried to build up stronger relationships with their suppliers, they were not able to reduce the upstream complaint rate. Supplier complaint rate increased from 1.0% in 2004 to 2.4% in 2009. One explanation is the increase of requirements concerning the quality of supplies on the manufacturers’ side. Another, more alarming interpretation, is the decrease in supplier quality due to increased outsourcing and increase in complexity of supply chains. It would be worthwhile to keep a close eye on this factor as outsourcing seems to be on rise and the complexities of managing quality of global supply chains is putting increased pressure on pharmaceutical companies’ quality departments. The implementation element “Process Management” includes the documentation, measurement, and improvement of processes. Comparing the results from 2004 to 2009, a slight decrease from 70% to 68% in “Process Management” implementation can be seen among the participating companies. Documentation and standardization based on cGMP in pharmaceutical manufacturing is established since decades and, consequently, very high scores regarding these practices are found. Of greater concern is the fact that

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measurement methods using statistical process control or process analytical technology and assessment using root-cause analyses (e.g., DMAIC cycle) are implemented only in some very advanced brandname companies' manufacturing sites. A remarkable development from 2004 to 2009 could be observed in the implementation of "Cross-functional product development". Its value increased from 30% to 68%during these 5 years. Generally, "Cross-functional product development" aims at the translation of customer requirements (external and internal customers) into high quality products. With focus on the manufacturing environment, it means the close link between development (product and process) and manufacturing. The increase in this category shows that pharmaceutical companies are concerned with the separation of development and manufacturing and has made significant improvements. By 2009, companies established a closer collaboration between the R&D and manufacturing departments with the ultimate objective to shorten the time for scale-ups by moving from "quality by inspection" to "quality by design". In 2009, manufacturing engineers are more involved in the development of products and necessary production processes. It could also be a reflection of headcount reduction in pharmaceutical R&D's necessitating engineers in development and manufacturing to assume multiple roles. Another improvement reveals the widespread understanding that it is essential to know what customers want in order to stay competitive by providing products that meet their requirements. Pharmaceutical companies were able to increase their implementation level in the category of "Customer Involvement" from 48% in 2004 to 73% in 2009. Customers now frequently give feedback on quality and delivery performance to pharmaceutical manufacturers leading to continuous improvement. Nonetheless, there is still room for improvement regarding the assessment of customer requirements and proactive management of key customers. Starting with a higher median value of 60% in the category "Supplier Quality Management" compared with "Customer Involvement", an increase to 66% could be observed. The category addresses the integration of suppliers into the internal quality system to ensure high quality levels. The vast majority of the companies mark quality as their number one criterion in selecting suppliers and not solely the product price. Furthermore, validation and qualification of suppliers play critical roles for pharmaceutical manufacturers. Yet, companies hesitate to deploy joint improvement programs with suppliers to increase overall process quality.

II. CONCLUSION

TQM is the most effective tool in quality management of pharmaceuticals. It is recommended strictly by many regulatory agencies but still it is not completely implemented in all the industries especially in India. As India is one of the largest exporters of pharmaceutical products across the globe, strict implementation of TQM is need of the hour in Indian context. Despite of extensive advancement in product development for real time online production and packaging monitoring, their limited utilization by majority of industries remains a major area of concern. In view of producing high quality medicines, this article is a plea for global regulating agencies and pharmaceutical industries for stricter enforcement and sincere adoption of TQM practices in industries.

As expected, due to the amount of personnel and financial resources put into efficiency increase in operations, the industry did make continuous steps throughout the systems TPM, TQM, JIT, and the underlying EMS towards the desired state of "Operational Excellence", though there are no grand-scale developments. It can be said that most of the companies are still working on the effectiveness side (TPM and TQM) rather than focusing on the efficiency side (JIT), pharmaceutical companies are trying to build stable running machines and stable processes before targeting the objective of low inventory. It can be argued that the industry average is not that advanced to already set a new focus on efficiency. Pharmaceutical companies took control over their former low asset utilization, managed to improve the efficiency of their quality systems, but are still far away from having any kind of "continuous flow", smooth production scheduling, or make-to-order manufacturing.

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