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Review Article

**A REVIEW ON TOTAL QUALITY MANAGEMENT IN THE  
PHARMACEUTICAL INDUSTRY****Mr. Darla Sujith<sup>1</sup>, Mr. V. S. Chandrasekaran<sup>2\*</sup>, Dr. K. Venugopal<sup>3</sup>**<sup>1</sup>Final year B Pharmacy, Krishna Teja Pharmacy College, Tirupati – 517 506.<sup>2</sup>Associate Professor, Department of Pharmaceutical Biotechnology, Krishna Teja Pharmacy College, Tirupati – 517 506.<sup>3</sup>Professor and Principal, Krishna Teja Pharmacy College, Tirupati – 517 506.**Abstract:**

*Total Quality Management (TQM) is a comprehensive management approach aimed at improving quality, productivity, and customer satisfaction across organizations, particularly in the pharmaceutical industry. TQM emphasizes continuous improvement, employee involvement, leadership, and customer focus. Originating after World War I and evolving through the contributions of quality experts like Deming, Juran, and Crosby, TQM integrates data-driven decision-making and process improvement to ensure high product standards. Key principles include customer-centricity, teamwork, leadership, and a systematic approach to management. In the pharmaceutical sector, TQM enhances product quality, minimizes defects, and reduces costs associated with poor quality, ultimately leading to improved customer satisfaction and competitive advantage. By fostering a culture of continuous improvement and mutual cooperation between employees and suppliers, TQM helps organizations achieve long-term success and adapt to market demands, ensuring the delivery of high-quality products and services.*

**Keywords:** *Quality, Management, employees, suppliers, pharmaceutical sector.*

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## 1. INTRODUCTION:

### 1. INTRODUCTION:

In nowadays, the pharmaceutical is a critical component of the health-care system, as it is responsible for the development and marketing of medicinal products for the benefit of society. poor medicine quality is accountable for health problems and results in a massive waste of capital and wealth for both the government and the person. people are intelligent and capable of selecting items that meet their needs. When it comes to the pharmaceutical industry, quality is one of the most important aspects, and it receives a lot of attention due to the competitive environment. As a result, maintaining quality with continual improvement in facilities is critical in the pharmaceutical industry. Regulatory agencies in several countries have identified some flaws in old quality management systems, and they are eager to adopt this total quality management (TQM). The concept of total quality control was applied in the early days, and quality was secured only based on quality control parameters. However, because it comprises complete records such as standard operating procedures for each process and step, validation records, master formula records, and batch production records, TQM entails building quality during the manufacturing of a pharmaceutical product (1,2).

As can be seen, the pharmaceutical industry has a lot of demand and prospects, and the Indian government and numerous Indian pharmaceutical businesses are moving into it. Though there are many options, there is also a lot of competition. As a result, in order to succeed, businesses must maintain high-quality products and services. Quality Management Systems (QMS) and Total Quality Management (TQM) are two examples of techniques that aim to enhance quality and performance to meet or exceed customer expectations. This can be accomplished by ensuring that all quality-related functions and processes are maintained throughout the organization. These are now being acknowledged as generic management tools that may be used in both the public and private sectors. Different aspects of quality management, guidelines, the idea, and techniques of TQM.

Total Quality Management (TQM) has been pivotal in contemporary management, influencing organizational performance since the 1990s through principles established by Deming, Juran, and Crosby. TQM emphasizes leadership, employee involvement, and customer focus, with practices like Deming's "14 Points" guiding implementation. While many organizations have successfully adopted TQM, others face challenges in achieving competitive

improvement due to factors like weak leadership support. In the era of digitization and Industry. TQM's principles of continuous improvement and customer satisfaction remain vital, requiring adaptation to integrate digital tools and foster innovation for enhanced performance.

### 2. ORIGIN of TQM:

Total quality management was created around the time of the First World War. Large-scale manufacturers were impacted by World War II, which resulted in the creation of low-quality goods on a regular basis. Manufacturers have deployed quality engineers and quality inspectors into the manufacturing lines and floors to address this quality issue. The involvement of quality inspectors during batch processing helped to reduce the number of non-compliances, failures, and deviations, resulting in improved quality. Following the First World War, it became regular practice to inspect the quality of manufactured goods. In the 1980s, the United States faced economic competition from Japan, so they became conscious of producing quality drug products and adopted the TQM approach to deal with it (2,3).

The theory of Statistical Quality Control was created by Dr. W. Edwards Deming (SQC). He proposed that while each item cannot be checked individually, a sample should be tested for quality and decisions made based on statistical methods. He proposed that a change in the routine and fixed manufacturing process would affect the quality of the final pharmaceutical product. As a result, if variation in the process is eliminated, the chances of quality change are reduced.

The quality management concepts were proposed by Dr . Deming. Top management commitment to quality, effective communication between higher-level employees and lower-level employees, continuous search for and rectification of quality problems, and company-wide training and education in quality are just a few of them. Quality, according to Joseph Juran, is "fitness for use." Juran is also credited with coining the phrase "Cost of Quality." He is the one who came up with the concept of the Quality Trilogy, i.e. Quality assurance, quality control, and quality improvement are all aspects of quality management. Philip B. Crosby coined the phrase "do it right the first time" and the concept of zero defects, arguing that no number of flaws is acceptable. Kaoru Ishikawa is well recognized for his work on cause-and-effect diagrams, popularly known as fishbone diagrams or Ishikawa diagrams (4).

Continuous improvement, or KAIZEN, is another notion of Total Quality Management. The Japanese pioneered the concept of gradual improvement. 'Small changes can be made quickly, easily, and continuously without any significant investment,' was

the idea behind this concept. Small changes can result in significant improvements for organizations, employees, and customers. It was dubbed 'Kaizen' by the Japanese, which means a regular habit of thinking up fresh ideas.

### 3. PRINCIPLES OF TOTAL QUALITY MANAGEMENT:



In the mid-1990s, the eight basic principles or elements of TQM was proposed by some well-known philosophers. These eight principles of TQM entirely work together to develop the process and yield customer satisfaction.

#### 3.1. CUSTOMER FOCUS:

The first and prime principle of total quality management (TQM) is to focus on the customers who are buying the products and services as well as potential customers. Customers are the people who justify the quality of the products and services. So, the company needs to ensure that the customers will feel that they have spent their money on a quality product if it can last long to fulfill demands. You can exceed customer satisfaction only when you know their needs. So, successful companies align their objectives with the client's needs (5).

#### 3.2. LEADERSHIP:

Leadership is essential in maintaining unity among employees to achieve interdependent goals (Evans, 2013). Although there are mainly three types of leadership in the industry, the democratic leadership style is the best to perform well. Leaders can form a convenient environment to work effectively inside the organization, in which all employees work to achieve the organization's goal. So, leadership seems to be a significant principle of total quality management.

#### 3.3. INVOLVEMENT OF PEOPLE:

People from every level give their all-out efforts and dedication to the organization's profits. The total employee commitment enables the industry to develop products and raise sales growth. So, all the

employees in the organization have to be well-trained, committed, and dedicated to achieving an interdependent goal on time. Additionally, the industry needs to create a responsive environment where every employee will be motivated to complete the task correctly. The employees' activeness, motivation, and retention can yield customer gratification. The involvement of people can produce effective teamwork. According to Evans (2013), three types of cooperation are vertical, horizontal, and inter-organization.

### **3.4. PROCESSES APPROACH:**

The company needs to improve the process consistently to yield sound output. A good result from the processes approach can bring customer satisfaction. Hence, TQM focuses on the process approach to assure the quality of the product or service.

### **3.5. SYSTEM APPROACH TO MANAGEMENT:**

Total quality (TQM) highlights executing the strategy systematically. The industry makes a proper implementation plan, and they collect data while applying those processes. The International Organization for Standardization (ISO) describes this principle: "Identifying, understanding, and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives."

### **3.6. CONTINUAL IMPROVEMENT:**

Continual improvement of the process is an essential step for every industry to make its customers satisfied. Therefore, TQM assists the company in keeping watching the constant improvement of the system to improve the service and product of the industry. Above all, continual improvement assists the company in achieving competitive advantages, and it is the most critical principle among the eight principles of TQM.

### **3.7. FACTUAL APPROACH TO DECISION MAKING:**

A factual approach to decision-making is another crucial principle of TQM. It eases making decisions based on the information collected from data. Making a decision based on facts is an effective way to achieve customer satisfaction. This principle uses the

actual method to collect and analyze data in order to make decisions for the company's progress.

### **3.8. MUTUAL BENEFICIAL SUPPLIER RELATIONSHIP:**

Mutual beneficial supplier relationship is another important principle of total quality management for building rapport with suppliers. It is also called reciprocity. Usually, a business is conducted by multiple combined departments, and each of the departments is assigned individual tasks, although the function of these departments is interconnected. The total quality management process helps all sections work combined to achieve an interdependent objective. The company uses visual aids and flowcharts to understand how employees perform perfectly. Executing total quality management (TQM) is not easy; TQM represents a significant cultural shift, so the company needs to implement it slowly and accurately (Evans, 2013).

### **4. THE KEY ELEMENTS OF THE TQM APPROACH ARE:**

#### **a) Focus on the customer:**

The organization's most important responsibility is to identify its customers (internal and external). Customers of the drug product may be external customers, while workers of the company may be internal customers. Organizations should think about and focus on each and every customer's expectations, with customer happiness as the primary goal (6,7,8).

#### **b) Employee Involvement:**

Because quality is the responsibility of every employee, the organization must utilize each employee's experience and knowledge in the process of quality improvement. The organization must involve all employees and urge them to participate actively in this movement so that they may contribute to the improvement of quality.

#### **c) Continual Improvement:**

Improving quality and maintaining it is a never-ending process in which each person consistently contributes to the improvement of company performance, process yield, and product or service attributes. The goal of continuous improvement is to increase quality at regular intervals and sustain it. This will, in turn, serve to improve the overall quality of the product or service, as well as the overall performance of the business.

**Table 1: TQM Eight Elements:**

<b>Foundation</b>		
The TQM is built on the principles of ethics, integrity, and trust to improve openness, fairness, and sincerity. Every employee can participate in TQM, and everyone should contribute fresh TQM ideas and concepts.		
<b>A</b>	<b>Ethics</b>	In each scenario, ethics is concerned with the good-bad or right-wrong. It is represented by organizational and individual ethics and is similar to two sides of a coin. Organizational ethics are set of rules that all employees must follow when performing their jobs. Personal ethics refers to personal rights and wrongs.
<b>B</b>	<b>Integrity</b>	Honesty, principles, values, fairness, commitment to the facts, and sincerity are all examples of integrity. It is the internal or external expectations of the client, and it deserves to be met.
<b>C</b>	<b>Trust</b>	Integrity and ethical behavior are the foundations of trust. Trust encourages complete engagement from all members, and TQM cannot be implemented without it. It's also crucial to guarantee consumer pleasure.
<b>Bricks</b>		
<b>D</b>	<b>Training</b>	Supervisors are exclusively responsible for running and implementing TQM within departments, as well as teaching employees TQM philosophies in order to increase production. Employee training focuses on improving interpersonal skills, teamwork, problem-solving, decision-making, job management performance analysis and improvement, business economics, and technical abilities
<b>E</b>	<b>Team work</b>	Teamwork is a fundamental component of TQM for a successful business, and as a result, problems will be solved faster and more effectively. Teams also help to improve processes and operations on a more permanent basis. Quality improvement teams or excellence teams (QITS), problem-solving teams (PSTS), and natural work teams are the three types of teams used by TQM enterprises (NWTs).
<b>F</b>	<b>Leadership</b>	It is the most crucial aspect of TQM. To give focus, clarity, and direction to increase quality, a supervisor must grasp TQM and present an inspiring vision, strategies, philosophies, beliefs, and goals.
<b>Binding Motor</b>		
<b>G</b>	<b>Communication</b>	It serves as a critical link between all aspects of the TQM house, from the foundation to the roof, and everything is held together by a strong communication mortar. Communication is defined as the proper and complete understanding of ideas among all members of a company, suppliers, and customers. Downward communication (the most common form of communication in an organization, such as presentations and discussions so supervisors can explain TQM to employees), upward communication (lower-level employees can provide suggestions to upper management to provide insight and constructive criticism to correct the situation that arises from the use of TQM, and it also builds a level of trust between them) (it breaks down barriers between departments and allows dealing with customers and suppliers in a more professional manner).
<b>Roof</b>		
<b>H</b>	<b>Recognition</b>	The last and final component of the system is recognition, which is given for both team and individual suggestions and accomplishments. Good performers can be recognized in front of departments, on performance boards, or in front of top management in a variety of ways (award banquets, plaques, trophies), places (good performers can be recognized in front of departments, on performance boards, or in front of top management), and times (award banquets, plaques, trophies) (Recognition like at time of in staff meeting, annual award banquets).



## 5. REQUIREMENTS FOR IMPLEMENTATION OF TQM:

**Table 2: Six TQM Required for Successful TQM Implementation**

<b>1</b>	<b>Commitment from employees</b>	All personnel of the firm must adhere to the TQM policies in order to increase quality.
<b>2</b>	<b>Culture of quality Improvement</b>	In order to encourage employee input and ensure effective administration of authorised work, the organisation must have a Quality Improvement Culture that is updated on a regular basis.
<b>3</b>	<b>Continuous improvement in Process</b>	TQM is a process, not a programme that necessitates continuous improvement in all linked policies, procedures, and controls established by management.
<b>4</b>	<b>Cooperation from Employees</b>	Employees' knowledge and cooperation are put to good use in the development of new, better plans and performance metrics.
<b>5</b>	<b>Focus on customer Requirements</b>	Customers expect faultless goods and services with zero faults in today's market, thus TQM processes must be prepared by focusing on customers' requirements and expectations from products and services in order to thrive in the long run and establish relationships with customers.
<b>6</b>	<b>Effective control Shall be laid down</b>	All documents or manuals of current good manufacturing practices must be included in the checklist of control policies (monitoring and measuring business performance) to repair any faults in the business process.

## 6. THE CONCEPTS OF TQM:

TQM is the latest breakthrough in the field of management where all activities are aimed at optimizing customer satisfaction, through continuous process improvement. according to Cascio (1995): "TQM, is a philosophy and a set guiding principles that represent the foundation of a continuously improving organization". According to Robbins (1996): "TQM, is a philosophy of management that is driven by the consistent attainment of customer satisfaction through the continuous improvement of all organizational processes". The opinions above show clearly that TQM activities are aimed at meeting customer expectations.

The working principle in question is Deming's working principle, namely: Plan, Do, Check, and Action. Gomez-Mejia, Balkin, Cardy, and Robert (1995) convince that TQM is a wide approach to improving the quality of all processes that lead to a final product or service. Tenner and Detoro (1992) state that combining the various teachings of quality gurus with practical experience has led to the development of a simple but effective model for implementing TQM (9,10,11).

Specifically, TQM has several benefits, both directly related to operational aspects of work life and those related to strategic organizational values. This is as stated by Cascio (1995): TQM requires a change in organization culture, a fundamental change in the

way individuals and groups approach their work and their roles in the organization, that is, from an

environment of distrust and fear of reprisal to one of openness and trust where creativity can flourish; from working as individuals to working as teams; from protection of organizational turfs to the break-down of departmental barriers; from an autocratic management style of direction and control to a softer style of a team leader and coach; from power concentrated at the top to power shared with employees; from a focus on results to focus on continuous improvement of the processes that deliver the result; and finally a change from making decision based on gut- feel to an analytic, fact-based approach to management. Cascio (1995) revealed that TQM is a philosophy and a series of instructions for organizations to make continuous improvements, which are formed from 7 components/ subsystems (12,13).

## 7. THE BENEFITS TQM:

- i. Increased involvement of workers/employees: TQM convinces everyone within the organization should have a clear understanding of what is required and how their processes relate to the business as a whole. Through TQM practices, work teams are used and workers are motivated and encouraged to control, organize, and improve processes, which are within their responsibilities (14).

- ii. Improved communication: Better communication can be done through the effective implementation of TQM principles in any organization. More open and frequent communication between people will be found, and they will view and treat each other as customers and suppliers (Anjard, 1998).
- iii. Increase productivity: TQM will change the organizational culture and create a pleasant work environment. Through effective delegation, empowerment, and full involvement of employees, problems can be identified and resolved at lower levels. So that the work process will bring results that are very efficient, and very consistent and productivity can be increased by decreasing cycle time.
- iv. Improved quality and reduced rework.” In the implementation of TQM, focus on work processes and improvements. Workers will place more emphasis on eliminating the root causes than on correcting the problem. Also, more future effort is put into clarifying requirements and proactively preventing the occurrence of deficiencies and errors.
- v. Increased customer satisfaction: Through open communication among workers, customers, and suppliers, the real voice of consumers can be more readily understood. Because quality operations also focus more on work processes and improvements, the company will provide better quality products/services to the market. Therefore increased customer satisfaction is achieved.
- vi. Reduced costs due to poor quality: Effective implementation of TQM will lead to significant reductions in costs due to poor quality such as scrap, rework, late completion, warranties, replacements, etc.
- vii. Increased competitive advantage: In summary, the ultimate advantage is to strengthen the competitive advantage of the organization to survive in the market. If TQM is successfully implemented, this will result in customer satisfaction and quality products/services provided at low prices. This can lead to increased sales to achieve profit and business growth goals.

### 8. CONCLUSION:

In conclusion, Total Quality Management (TQM) is essential for fostering continuous improvement and customer satisfaction, especially in the

pharmaceutical industry. By focusing on principles such as customer-centricity, employee involvement, leadership, and process improvement, TQM helps organizations enhance product quality, reduce costs, and maintain a competitive edge. Its emphasis on data-driven decision-making and mutually beneficial supplier relationships creates a sustainable framework for long-term success. As companies strive to meet growing demands, the integration of TQM ensures that they deliver high-quality products and services while adapting to the evolving needs of the market and customers.

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