

Achieving operational excellence: Key factors in total quality management for pharmaceutical industry

Aroon Adulapuram, Maheshwari Annaladas *, Bhumika Allikanti and Amena kausar

Sarojini Naidu Vanitha Pharmacy Mahavidyalaya, Tarnaka, Hyderabad, India.

World Journal of Biology Pharmacy and Health Sciences, 2024, 18(02), 327–331

Publication history: Received on 03 April 2024; revised on 11 May 2024; accepted on 13 May 2024

Article DOI: <https://doi.org/10.30574/wjbphs.2024.18.2.0275>

Abstract

The implementation of total quality management always concerned by top management within organization. TQM is the process of involving all employees of organization in its continual improvement to achieve customer satisfaction. The aim of this study is focused at elements & key success factors implemented TQM process. Quality is critically important ingredient to organizational success achieved by TQM, which aimed at prevention of defects rather than detection of defects.

Keywords: Quality Assurance; Quality Control; Total Quality Management; Elements.

1. Introduction

The basic goal of TQM is to involve all levels & functions of an organization in continually meeting & exceeding the customer's expectations of their daily operations, products or services.

The assurance of quality of the product depends on more than just proper sampling & adequate testing of various components & dosage forms. Quality assurance must establish control or check points to monitor the quality of product as it processed & completion of manufacturing.

Quality assurance policy become the most important goal of pharmaceutical industry. The Quality assurance & quality control concept is to develop & follows standard operating procedures. World Health Organization (WHO) has issued primary or fundamental regulation their own requirements for GMP. In USA, Food & Drug Administration (FDA) has mandate the marketed drug product to be safe effective, quality & purity. The FDA has issued regulatory guidelines known as current good manufacturing practice (CGMP). [1,2]

The total quality management (TQM) includes the following [3,7]

1. Customer should be satisfied.
2. To provide employees with tools.

TQM can be difficult to achieve & maintain whether a company is striving to maintain high level of quality for its own sake or keep up with ISO, FDA, EMEA regulation. The very primary step is implementing TQM is to access the organization present situation or accessing the reality of the term.

* Corresponding author: Maheshwari Annaladas

1.1. Benefits of TQM

1. Improvement in product quality
2. Improvement in product design
3. Improvement in product flow
4. Improvement in employee morale & quality consciousness
5. Improvement in product service
6. Improvement in market place acceptance

1.2. Economic improvement benefits

1. Reduction in operating costs
2. Reduction in operating losses
3. Reduction in field service costs
4. Reduction in liability exposure

1.3. Advantages of TQM

1. Improves dignity, errors & problems are identified & sorted
2. High – quality senior staff by increased responsibility, team performance
3. Low cost
4. Minimize waste or defective production

1.4. Disadvantages of TQM

1. Cost of initial production
2. Employees may not agree to change

2. Key elements of TQM

2.1. Focus on the customer

The organizations most important responsible is to identify the customers (internal & external). Customers of the drug product may be external customers while workers may be internal customers. Organizations should think about & focus on each & every customer expectations with customer happiness as primary goal.

2.2. Employee improvement

Quality is the responsibility of every employee, the organization must utilize each employees experience & knowledge in quality improvement.

2.3. Continual improvement

It is never ending process in which each person contribute to improvement of company performance process yield & product. The goal of continuous improvement to increase quality at regular intervals and sustain it. [3]

It includes mainly 8 elements.

This elements are divided into four groups according to their functions. These groups are:

- **Foundation** It includes ethics, integrity, trust.
- **Building Bricks** It includes training, teamwork, leadership.
- **Binding mortar** It includes communication.
- **Roof** It includes recognition

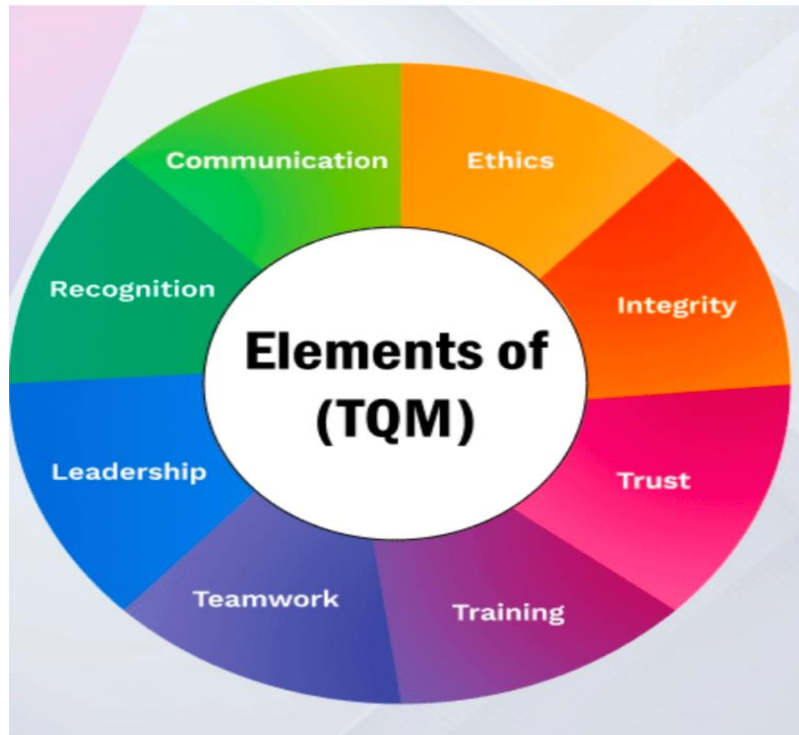


Figure 1 Elements of Total Quality Management (TQM) for success

3. Foundation

The TQM is built on the principles of ethics, integrity, and trust to improve openness, fairness, and sincerity.

3.1. Ethics:

Ethics is concerned with good-bad or right-wrong. It is a two-faceted subject represented by organizational & individual ethics. Organizational ethics establish a set of rules that all employees must follow when performing their jobs. Individual ethics include personal rights or wrongs.

3.2. Integrity

It implies honesty, principles, values, fairness, commitment to facts and sincerity. It is internal or external expectations of clients & it deserves to be met.

3.3. Trust

Integrity & ethical behaviour are the foundation of trust. Trust encourages complete improvement that encourages pride of ownership.

It ensures customer satisfaction.

4. Building Blocks

Bricks are piled on top of a strong foundation of trust, ethics, integrity to reach a root of recognition includes

4.1. Training

Training is very important for employees to be highly productive. Employee training focuses on improving & interpersonal skills, team work, problem solving, decision making, job management, performance analysis & business economics, and technical skills.

4.2. Team work

It is the fundamental component of TQM. Team help to improve processes & operation on more permanent basis. Quality improvement teams or excellence teams (QITS), problem solving teams (PSTs) & natural work teams are 3 types of teams used by TQM enterprises (NWTS).

4.3. Leadership

It is a crucial aspect of TQM. To give focus, clarity & direction to increase quality, a supervisor must grasp TQM & present an inspiring vision, strategies, beliefs & goals.

4.4. Binding Mortar

4.4.1. Communication

It serves as critical link between all aspects of TQM house from foundation to roof & it is held together by strong communication mortar. It includes downward communication motor (the most common form of communication in an organization such as presentation 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). Communication is defined as the proper and complete understanding of ideas among all members of a company, suppliers, and customers.

5. Roof

5.1. Recognition

The last & final element in entire system is recognition which given for both team & individual suggestions & accomplishments. Good performers can be recognized in front of departments, on performance boards or in front of top management, detecting & recognizing contribution is the most important job of a supervisor. [4]

6. Success factors

According to critical success factors (CSFs) of TQM can be described in the best practice of TQM implementation.

Mainly 10 key success factors of TQM which were critically important including strategic quality power, quality culture, customer and employees relationship, supplier management, leadership, communication, teamwork, quality improvement [5]. Further Black SA argued that TQM has become a significantly important aspect for company operating in hospitality industry; therefore the companies should focus extensively in strategic quality management to achieve the desired goal & objectives in most profitable manner [6].

6.1. Focus on the customer

TQM emphasizes understanding & exceeding patient expectation & requirements.

6.2. Continuous improvement:

TQM as continuous, ongoing company wide process to evaluate process, identification & eliminate errors. It is facilitated by data analysis, regular quality improvement.

6.3. Involve entire work force

It is empower all employees & encourage teamwork for improvement, proper solutions & take ownership of their roles.

6.4. Clear communication

Keeping everyone informed about TQM goals, progress & challenges.

6.5. Recognize quality achievements

The financial & non – financial in center & rewards to TQM to encourage pride & teamwork

7. Conclusion

In conclusion, achieving operational excellence through Total Quality Management (TQM) in the pharmaceutical industry is paramount for ensuring product quality, customer satisfaction, and organizational success. This paper has highlighted key elements and success factors essential for implementing TQM effectively. By focusing on customer satisfaction, continual improvement, employee involvement, clear communication, and recognition of quality achievements, pharmaceutical companies can drive positive outcomes such as improved product quality, design, flow, and employee morale. Moreover, adherence to ethical principles, integrity, and trust forms the foundation of TQM, fostering an environment of openness, fairness, and sincerity. Embracing these principles and practices can lead to economic benefits, reduced operating costs, and enhanced market acceptance, ultimately positioning pharmaceutical companies for sustained growth and competitiveness in today's dynamic healthcare landscape.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

Reference

- [1] Enders JE. Quality assurance and control. In: Gennaro AR. (Ed.). Remington: The Science and Practice of Pharmacy, 20th Ed., Vol. I. Lippincott Williams & Wilkins, New York. 2000. p. 980-985.
- [2] Lachman L, Hanna SA, Lin K. Quality control and assurance. In: Lachman L, Lieberman HA, Kanig JL. (Eds.). The Theory and Practice of Industrial Pharmacy. 2nd Ed., Verghese Publishing House, Bombay. 1976. p. 804-855.
- [3] Bhaskar Mazumdar, 2011, Total Quality Management in Pharmaceuticals: A Review, International Journal of PharmTech Research, Vol. 3, No. 1, PP 365-375
- [4] <https://ijcrt.org/papers/IJCRT2203154.pdf>
- [5] Amin, Muslim, Aldakhil A M, Wu c, and Razaeei sajad. "The structural relationship between TQM, employee satisfaction and hotel performance." Int J Contemporary Hospitality Manag 29 (2017): 1256-78.
- [6] Key success factors of total quality management (tqm) for the hospitality sector. a critical review of the literature Dr. Mudassar Hussain* Dr. Junaid Khan*
- [7] S Bhandari and Ashish Baldi, 2014, Total Quality Management of Pharmaceuticals: Recent Approaches and Advancement ,Advance Research in Pharmaceuticals and Biologicals, Vol. 4 (II), pp 655-663
- [8] International Conference on Harmonisation, (ICH) Harmonised Tripartite Guideline, June 2006, ICH Q9: Quality Risk Management, <http://www.ich.org>
- [9] Sharma S. and Bodla E.B., 2014, Pharmaceutical Quality Management System: A Review, International Journal of Drug Regulatory Affairs, 2(3), 67-78
- [10] B. Mazumder, S. Bhattacharya, A. Yadav, Total quality management in pharmaceuticals: a review, Total Quality Management.Vol-3, 365-375.
- [11] A. Mitra, 2016, "Fundamentals of quality control and improvement", John Wiley & Sons, vol-4, II, 25-30
- [12] S. B. B. Bhandari, A. Baldi, 2014, "Total quality management of pharmaceuticals: recent approaches and advancements total quality management of pharmaceuticals" recent approaches and advancements.Vol-4, II, 655-660
- [13] A review article of total quality management in pharmaceuticals <https://ijrpr.com/uploads/V3ISSUE6/IJRPR5040.pdf>