

**TOTAL QUALITY MANAGEMENT PRACTICES IN PHARMACEUTICAL INDUSTRY****K. Vijay Kumar*¹ and Dr. R. Sivaram Prasad²**¹Chalapathi Institute of Pharmaceutical Sciences, Guntur, Andhra Pradesh, India.²Research Director, Acharya Nagaruna University, Guntur, Andhra Pradesh, India.***Corresponding Author: K. Vijay Kumar**

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ABSTRACT

Quality management is a boom in Indian pharmaceutical area and is one such approach along with government regulatory requirements. TQM improves quality and performance in pharmaceutical products and meet customer expectations. The objective of TQM meets important goals of the industry. Quality control, good manufacturing practice and quality assurance assures quality, safety and efficacy of the drug products. TQM leads to organization success and helps in reaching organization objectives. TQM prevents defects in pharmaceutical products and reduces the wastage of raw materials.

KEYWORDS: GMP, Quality control, Quality assurance, Pharmaceutical products.**INTRODUCTION**

An effective quality assurance policy with defined mission and objectives is the most important goal of pharmaceutical industry. The concept of quality assurance and quality control together develops towards assuring the quality, safety and efficacy of pharmaceutical products. Thus, quality is critically important ingredient to organizational success today, which can be achieved by total quality management (TQM), an organizational approach that focuses on quality as an over arching goal, aimed at the prevention of defects rather than detection of defects. Present work attempts to furnish a wide overview of the TQM concept and the management means leading to quality improvement of pharmaceuticals.

The maintenance of quality with continuous improvement in facilities is very important in pharmaceutical industries. The pursuit of quality being approached through the concept of total quality management (TQM) system which is aimed at prevention of defects rather than detection of defects. Total quality management is a management system for a customer oriented organization that involves all employees in continual improvement of all aspects of the organization. TQM uses strategy, data, and effective communication to integrate the quality principles into the culture and activities of the organization. TQM functions on the introduction of quality of products and process is the responsibility of everyone who is involved with the creation or consumption of the products or services offered by an organization. TQM capitalizes on the involvement of management, workforce, suppliers and

even customers, in order to meet or exceed customer expectations. The nine common TQM practices are cross-functional product design, process management, supplier quality management, customer involvement, information and feedback, committed leadership, strategic planning, cross-functional training and employee involvement.

To be effective in improving quality, TQM must be supported at all levels of a firm, from the highest executive to the lowest-level hourly employee. TQM extends the definition of quality to all functional areas of the organization, including production, marketing, finance, and information systems. The process begins by listening to customers' wants and needs and then delivering goods and services that fulfill these desires. TQM even expands the definition of customer to include any person inside or outside the company to whom an employee passes his or her work. This notion encourages each member of the organization to stay focused on quality and remain fully aware of his or her contribution to it and responsibility for it. The TQM philosophy focuses on teamwork, increasing customer satisfaction, lowering costs, and implementing quality at all levels. Organizations implement TQM by encouraging managers and employees to collaborate across functions and departments, as well as with customers and suppliers, to identify areas for improvement, no matter how small or big. Teams of workers are trained and empowered to make decisions that help their organization achieve high standards of quality. Organizations shift responsibility for quality control from specialized departments to all employees. Thus,

total quality management means a shift from a bureaucratic to a decentralized approach to control.

BENEFITS OF TOTAL QUALITY MANAGEMENT

Total quality management is defined an integrated organizational effort which has been designed to improve quality at every level in organization and an effective TQM program has numerous benefits. Financial benefits include lower costs, higher returns on sales and investment, and the ability to charge higher rather than competitive prices. Other benefits include improved access to global markets, higher customer retention levels, less time required to develop new innovations, and a reputation as a quality firm. Only a small number of companies use TQM because implementing an effective program involves much time, effort, money, and patience. However, firms with the necessary resources may gain major competitive advantages in their industries by implementing TQM.

IMPLEMENTATION OF TQM IN PHARMACEUTICALS:

Either its Pharmaceuticals, medical devices, biotech or host of other life sciences manufacturer, Total Quality Management can be difficult to achieve and maintain whether a company is striving to maintain high level of quality its own sake or keep up with ISO, FDA, EMEA Regulations, Total quality Management cannot be easily achieved without considerable organizational and human resources. Total Quality Management is a method by which management and employees can become involved in the continuous improvement process of the production of goods and services. It is a combination of quality and management tools aimed at increasing business and reducing losses due to wasteful practices. Total Quality is a description of the culture, attitude and organization of a company that strives to provide customers with products and services that satisfy their needs. The culture requires quality in all aspects of the company's operations, with processes being done right the first time and defects and waste eradicated from operations.

TQM views an organization as a collection of processes. It maintains that organizations must strive to continuously improve these processes by incorporating the knowledge and experiences of workers. The simple objective of TQM is "*Do the right things, right the first time, every time*". TQM is infinitely variable and adaptable. Although originally applied to manufacturing operations, and for a number of years only used in that area, TQM is now becoming recognized as a generic management tool, just as applicable in service and public sector organizations. There are a number of evolutionary

strands, with different sectors creating their own versions from the common ancestor. TQM is the foundation for activities, which include:

- Commitment by senior management and all employees
- Meeting customer requirements
- Reducing development cycle times
- Just In Time/Demand Flow Manufacturing
- Improvement teams
- Reducing product and service costs
- Systems to facilitate improvement
- Line Management ownership
- Employee involvement and empowerment
- Recognition and celebration
- Challenging quantified goals and benchmarking
- Focus on processes / improvement plans
- Specific incorporation in strategic planning

INDIAN PHARMACEUTICAL INDUSTRY

From a market size of USD 12.6 billion in 2009, the Indian pharmaceutical market will grow to USD 55 billion by 2020 with the potential to reach USD70 billion in an aggregate growth scenario. A pessimistic scenario characterized by regulatory controls and economic slowdown, the market will be depressed and is expected to reach USD 35 billion.

The Indian pharmaceutical industry mainly comprises of Indian subsidiaries of Multi National Companies (Glaxo Smithkline, Merck, Pfizer etc.), Indian owned companies (Ranbaxy, Dr. Reddy's, Cipla, Glenmark, Cadila) and numerous small scale industries scattered in all parts of India. These companies can also be classified on the basis of annual turnover, number of patents, number of employees and number of formulations.

In this paper, an attempt has been made to survey and review the Quality Management Practices including ISO implementation and further analyze the significant factors affecting the implementation of TQM in Indian pharmaceutical industries. The questionnaire has been modified and customized to the specific requirements of the Indian Pharmaceutical Industry. Initially this questionnaire was circulated to select respondents in the Indian pharmaceutical industry as part of the pilot study. Based on the responses received in the pilot study, the main factors affecting the implementation of Total Quality Management are: Top Management Commitment, Leadership, Quality Management, People Management and Training, Customer Focus and Supplier Quality. The importance of these factors in the context of the Indian Pharmaceutical Industry is tabulated below:

| Factor affecting TQM | Importance of the Factor in the context of Indian Pharmaceutical Industry |
|-----------------------------|--|
| Top Management Commitment | Top management commitment was found to be the most significant factor affecting the implementation of Total Quality Management. Top management of the respondent companies assumed responsibility for quality. It was found that the level of commitment and involvement shown by the senior |

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|--------------------------------|--|
| | management had noticeable effects on the success of the company. |
| Leadership | Leadership is an important factor for Total Quality Management. An effective and dynamic leader can lead a successful team and subsequently make a profitable organization |
| Quality Management | Quality management includes availability of quality information as well as usage of quality information. Timely and accurate information about the manufacturing process is important to control the process and reduce defective products. Immediate problem solving keeps the process in control. Similarly quality information usage is also an important feature of quality information management. Although quality information is available; only proper and effective use of it leads to quality improvement. |
| People Management and training | Employee training is an important factor of quality management. Training is an efficient way to increase employees' ability to perform better. An organization which fully utilizes the skills of its workers' ability is on its way to achieve organizational objectives |
| People Management and training | The main objective for a product or service design is to meet or exceed the customers' expectation and thus to satisfy the customer while making a reasonable profit. Customers are the driving force for product and service design. A customer oriented or customer focused organization maintains its competitive advantage. |
| Supplier & Vendor Quality | Supplier and vendor quality is also an important dimension of quality management as defective materials, parts and services lead to product and process quality problems. Maintaining good supplier and vendor relationship is acknowledged as a key factor in maintaining competitive advantage. |

The responses from the pilot study were encouraging. The questionnaire is being modified to encompass the specific requirements of all companies in the Industry. Statistical analysis would be done using SPSS. Finally a linkage between Total Quality Management Practices and Indian Pharmaceutical Industries' Performance will be established.

CAUSES OF FAILURES IN IMPLEMENTATION OF TQM APPROACH

Total quality management is proven strategy that has yielded significant financial benefits in many pharmaceutical companies. Yet quality efforts failed and yielded marginal results in some other companies. Studies showed that only one third of the companies had obtained significant results, one third were dissatisfied and one third has achieved moderate results. According to Brown, Hitchcock and Willard below mentions are reasons which come which can come in the boulevard of implementation:

- Focusing only on short term financial results to the exclusion of systems improvement.
- Quality Improvement requires change in thinking to manage the underlying systems.
- Interfering of managers in teamwork.
- Sloppy procedures and processes
- Lack of Understanding of TQM approach
- Many Layers in the organizational structure
- Lack of adequate training and education
- Limited resources

CONCLUSION

TQM encourages participation amongst employees, managers and organization as whole. Using quality management reduces rework nearly to zero in an achievable goal. The responsibilities either its professional, social, legal one that rest with the pharmaceutical manufacturer for the assurance of quality of product are tremendous and it can only be achieved by well organized work culture and complete engagement of

the employees at the work place. It should be realized that National & International Regulations must be implemented systematically and process control should be practiced rigorously. Thus quality is critically important ingredient to organizational success today which can be achieved by TQM, an organizational approach that focuses on quality as an over achieving goals, aimed at aimed at the prevention of defects rather than d.

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