STATE OF TOTAL QUALITY MANAGEMENT IN PHARMACEUTICAL INDUSTRY: LITERATURE REVIEW

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Abstract:

Total Quality management is a crusade in Indian pharmaceutical industry and is one such approach along with government regulatory requirements that seeks to improve quality and performance in Pharmaceuticals which will meet or exceed customer expectations. An effective quality assurance policy with defined mission and objectives is the most important goal of pharmaceutical industry. Quality assurance and quality control together develops towards assuring the quality, safety and efficacy of pharmaceutical products. They should strive to achieve perfection by continuously improving the business and production processes. Thus, quality is critically important ingredient to organizational success, which can be achieved by total quality management TQM. It is an approach that arching goal, aimed at the prevention of defects rather than detection of defects. Present review attempts to furnish overview of the TQM concept and the management means leading to quality improvement of Pharmaceuticals.

Key words: Total Quality management, Pharmaceutical, GMP, Implementation.

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INTRODUCTION:

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 is not an easy concept to introduce into businesses - particularly those that have not traditionally concerned themselves too much with understanding customer needs and business processes. In fact - many attempts to introduce TQM fail. TQM uses strategy, data, and effective communication to integrate the quality principles into the culture and activities of the organization. TQM functions on the premise that the quality of products and processes 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. Six empirical studies by Cua, McKone, and Schroeder (2001) identified the nine common TQM practices as cross-functional product design, process management, supplier quality management, customer involvement, information and feedback, committed leadership, strategic planning, cross-functional training, and employee involvement. The concept of TQM rests largely on five principles:

1. Produce quality work the first time
2. Focus on the customer.
3. Have a strategic approach to improvement.
4. Improve continuously.
5. Encourage mutual respect and teamwork.

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. In a restaurant, for example, the cooks' customers are the waiters and waitresses.

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.

EVOLUTION OF QUALITY:

Before the concepts and ideas of TQM were formalised, much work had taken place over the centuries to reach this stage. During the early days of manufacturing, an operative's work was inspected and a decision made whether to accept or reject it. As businesses became larger, so too did this role and full time inspection jobs were created. Accompanying the creation of inspection functions, other problems arose:

- More technical problems occurred, requiring specialised skills, often not possessed by Production workers
- The inspectors lacked training
- Inspectors were ordered to accept defective goods, to increase output
- Skilled workers were promoted into other roles, leaving less skilled workers to perform the Operational jobs, such as manufacturing

These changes led to the birth of the separate inspection department with a "chief inspector", reporting to either the person in charge of manufacturing or the works manager. With the creation of this new department, there came new services and issues, e.g. standards, training, recording of data and the accuracy of measuring equipment. Hence a need of the quality control department evolved.

In the 1920's statistical theory began to be applied effectively to quality control, and in 1924 Shewhart made the first sketch of a modern control chart. His work was later developed by Deming and the early work of Shewhart, Deming, Dodge and Romig constitutes much of what today comprises the theory of statistical process control (SPC). However, there was little use of these techniques in manufacturing companies until the late 1940's. At that time, Japan's industrial system was virtually destroyed, and it had a reputation for cheap imitation products and an illiterate workforce. The Japanese recognised these problems and set about solving them with the help of some notable quality gurus – Juran, Deming and Feigenbaum.

In the early 1950's, quality management practices developed rapidly in Japanese plants, and become a major theme in Japanese management philosophy, such that, by 1960, quality control and management had become a national preoccupation.

In 1969 the first international conference on quality control, sponsored by Japan, America and Europe, was held in Tokyo. In a paper given by Feigenbaum, the term "total quality" was used for the first time, and referred to wider issues such as planning, organisation and management .responsibility. Ishikawa gave a paper explaining how "total quality control" in Japan was different, it meaning "companywide quality control", and describing how all employees, from top management to the workers, must study and participate in quality control. Companywide quality management was common in Japanese companies by the late 1970's.

The quality revolution in the West was slow to follow, and did not begin until the early 1980's, when companies introduced their own quality programmes and initiatives to counter the Japanese success. Total quality management (TQM) became the centre of these drives in most cases. In a Department of Trade & Industry publication in 1982 it was stated that Britain's world trade share was declining and this was having a dramatic effect on the standard of living in the country. There was intense global competition and any country's economic performance and reputation for quality was made up of the reputations and performances of its individual companies and products/services.

The British Standard (BS) 5750 for quality systems had been published in 1979, and in 1983 the National Quality Campaign was launched, using BS5750 as its main theme. The aim was to bring to the attention of industry the importance of quality for competitiveness and survival in the world market place. Since then the International Standardisation Organisation (ISO) 9000 has

become the internationally recognised standard for quality management systems. It comprises a number of standards that specify the requirements for the documentation, implementation and maintenance of a quality system. TQM is now part of a much wider concept that addresses overall organisational performance and recognises the importance of processes. There is also extensive research evidence that demonstrates the benefits from the approach.

As we move into the 21st century, TQM has developed in many countries into holistic frameworks, aimed at helping organisations achieve excellent performance, particularly in customer and business results. In Europe, a widely adopted framework is the so-called "Business Excellence" or "Excellence" Model, promoted by the European Foundation for Quality Management (EFQM), and in the UK by the British Quality Foundation (BQF)."

BENEFITS OF TOTAL QUALITY MANAGEMENT:

Total quality management as defined an integrated organizational effort which has been designed to improve quality at every level in organization. It has been also defined as Quest of excellence, fitness for use value for money, customer satisfaction etc. and so 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. Ten year study by Hendricks and Singhai showed there is strong link between TQM and financial performance. 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.

INDIAN PHARMACEUTICAL INDUSTRY:

India's pharmaceutical industry is now the third largest in the world in terms of volume. Its rank is 14th in terms of value. Between September 2008 and September 2009, the total turnover of India's pharmaceuticals industry was US$ 21.04 billion. The domestic market was worth US$ 12.26 billion. This was reported by the Department of Pharmaceuticals, Ministry of Chemicals

and Fertilizers. As per a report by IMS Health India, the Indian pharmaceutical market reached US$ 10.04 billion in size in July 2010. A highly organized sector, the Indian Pharmaceutical Industry is estimated to be worth $ 4.5 billion, growing at about 8% to 9% annually. It is always becomes imperative for Indian pharmaceutical industry to search for new competitive advantages to remain in competition and business. One of the strategies that differentiate a company from its competitors is quality.

Apart from safety pharmaceutical industry is heavily regulated and reasons are obvious: mistake in product design or production can have severe, even fatal, consequence for patients. To ensure their quality and safe product pharmaceutical companies build their quality approach around Good manufacturing practices, Good laboratory practices, Good clinical practices and In-house standard operating procedure.

Total Quality Management (TQM) is one such approach that seeks to improve quality and performance which will meet or exceed customer expectations. This can be achieved by integrating all quality related functions and processes throughout the company. The principles enunciated in TQM are universal and they can be utilized for improving the quality of any product. It is now becoming recognized as a generic management tool, just as applicable in service sector organizations. There are a number of evolutionary strands, with different sectors creating their own versions from the common ancestor. In this Paper the principle and tools of TQM, importance of information technology in implementing TQM and effect of the TQM principles on pharmaceutical industries are studied.

The concept of quality assurance and quality control develops and follows standard operating procedures (SOP) directed towards assuring the quality, safety and efficacy. World Health Organization (WHO) has issued a primary or fundamental regulation to pharmaceutical industries entitled good manufacturing practice (GMP) for pharmaceuticals. Based on WHO GMP, many countries have formulated their own requirements for GMP. In USA, as the Food and Drug Administration (FDA) has a mandate that the marketed drug product be safe effective, the drug product must meet certain criteria for quality and purity. The FDA has issued regulatory guidelines known as current good manufacturing practice (cGMP) and good laboratory practice (GLP) to assure the public that the marketed drug product has been properly manufactured and clinically tested respectively. According to FDA regulations, a drug product that does not meet

the GMP requirements is considered unacceptable. Thus, quality is critically important ingredient to organizational success today which can be achieved by total quality management (TQM) in an organization wide approach that focuses on quality as an overarching goal. The basis of this approach is the organizational units should be working harmoniously to satisfy the customer. Since the customer's needs are in constant flux, the organization must strive to continuously improve its system and practices. The TQM perspective views quality as the central purpose of the organization, in contrast to the focus on efficiency advocated by the operational perspective.

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 organisational 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 Management is a management approach that originated in the 1950's and has steadily become more popular since the early 1980's. 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

TQM can be across various sectors at different levels, in all activities, by all personnel, in Manufacturing, Marketing, Engineering, R&D, Sales, Purchasing, HR, etc.

IMPLEMENTATION PRINCIPLES AND PROCESSES IN PHARMACEUTICALS:

The very primary step in implementing TQM is to accesses the organizations present situation or can be said as accessing the reality of the firm. And to accesses the reality one has to know the organization history, its current needs, and participating events leading to TQM and the existing employees conditions of work culture. If one did not have the current realities then should delay the implementation process to get best implementation done.

TQM will be easier to implement in an organization when the organization has tack record of being able to change the way it operates whenever needed. To get the previous history of the organization management audit is the best possible way. It is a good assessment tool to identify

current levels of organizational functioning and areas in need of change. An organization should be basically healthy before beginning TQM. If it has significant problems such as a very unstable funding base, weak administrative systems, lack of managerial skill, or poor employee morale, TQM would not be appropriate. Beckhard and Pritchard (1992) have outlined the basic steps in managing a transition to a new system such as TQM: identifying tasks to be done, creating necessary management structures, developing strategies for building commitment, designing mechanisms to communicate the change, and assigning resources.

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:

- Focussing 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 organised

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

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