TOTAL QUALITY MANAGEMENT IN WHOLE PHARMACEUTICAL DEPARTMENT

[1]Freny Patel, [1]Neha Tiwari, [2]Pragnesh Patni
[1]Research Scholar, [2]HOD, [3]Principal
[1,2]Department of pharmaceutical Quality Assurance, A-one Pharmacy Collage, Enasan, Ahmedabad, Gujrat, India,
[3]Department of pharmacology, A-one Pharmacy Collage, Enasan, Ahmedabad, Gujrat, India.

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. Implementation of an effective quality assurance policy 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. 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.

Index terms - Quality assurance, total quality control, total quality management (TQM).

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. The pharmaceutical industry, as a vital segment of the health care system conducts research, manufacturing and marketing of pharmaceuticals and biological products and medicinal devices used for the diagnosis and treatment of diseases. 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[1].

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[1,2]. 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. Thus, total quality management means a shift from a bureaucratic to a decentralized approach to control[10].

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[1,2].

QUALITY:

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; delighting the customer etc. Quality is a very commonly used term but can be described very vaguely. Quality is an unusually slippery concept, easy to visualize and yet difficult to define. It is a matter of feeling and the definition varies from person to person depending on the perspective in which defined[2].

The eight dimensions of quality, which is a critically important ingredient to organizational success, are as follows.

1. **Performance:** Product's primary operating characteristics.
2. **Features:** Supplements to a product's basic functioning characteristics.
3. **Reliability:** A probability of not malfunctioning during a specified period.
4. **Conformance:** The degree to which a product's design and operating characteristics meet established standards.
5. **Durability:** A measure of product life.
6. **Serviceability:** The speed and ease of repair.
7. **Aesthetics:** How a product looks, feel, tastes and smells.
8. **Perceived quality:** As seen by a customer.

EVALUATION OF QUALITY MANAGEMENT

Many of the tools and techniques that were used to identify quality problems and take corrective action date back decades earlier. The need for improved product quality emerged in the 1980s, when it became apparent that the United States was logging behind some industrialized countries, most notably Japan, in the area of product quality. For instance, Walter A. Shewhart, a Bell Labs statistician, developed a set of methods in the 1920s that were designed to ensure standardization and reduce quality defects[11].

Introduction of Taylor's "scientific management approach" leads to strict division of labours and creation of quality control on the basis of inspection conducted by a specialist unit in the organization. Application of statistical methods in sampling and inspection produced statistical production control (SPC) methods. The quality control and inspection focuses on detection of defective products, identification of products not meeting their specifications and not allowing those to leave the factory gate[3,4].

TQM is infinitely variable and adaptable. Although originally applied to manufacturing sector and for a number of years used only in that area it is very much suitable in pharmaceutical industries tool[16].

TOTAL QUALITY MANAGEMENT

It may also be defined as performance superiority in delighting customers. The means used are people, committed to employing organizational resources to provide value to customers, by doing the right things right the first time, every time [2,4].

Therefore, total quality management (TQM) means:

1. Satisfying customers first time, every time;
2. Enabling the employees to solve problems and eliminate wastage;
3. A style of working, a culture more than a management technique;
4. Philosophy of continuous improvement, never ending, only achievable by/or through people.

British Quality Association offers three alternative definitions of TQM:

1. The first focuses on soft quality characteristics and may be defined as 'integrative management' concept for continuously improving the quality of good/services delivered through the participation of all levels and functions.
2. The second focus on 'hard' production/operation management type of view involving less discretion for employees. It may be defined as a 'set of techniques and procedures used to reduce or eliminate variation from a production/process or service delivery system in order to improve efficiency, reliability and quality.
3. The third definition is a mixture of hard and soft comprising 3 features and obsession with quality, need for a scientific approach and the view that all employees are involved in this process.

The key elements of the TQM approach are:

1. Focus on the customer: It is important to identify the organization's customers. External customers consume the organization's product or service. Internal customers are employees who receive the output of other employees. Customer focus positively affects inventory management performance, sales, aggregate firm work[12-15].

2. Employee Involvement: Since the quality is considered the job of all employees, employees should be involved in quality initiatives. Front line employees are likely to have the closest contact with external customers and thus can make the most valuable contribution to quality. Therefore, employees must have the authority to innovate and improve quality.

3. Continuous improvement: The quest for quality is a never-ending process in which people are continuously working to improve the performance, speed and number of features of the product or service. Continuous improvement means that small, incremental improvement that occurs on a regular basis will eventually add up to vast improvement in quality.

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[10].

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.

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. The TQM perspective views quality as the central purpose of the organization, in contrast to the focus on efficiency advocated by the operational perspective[10].

IMPLEMENTATION OF TQM IN PHARMACEUTICALS:

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[10].

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"[10].

MANAGING TOTAL QUALITY

The most pervasive approach to managing quality has been called total quality management (TQM) – a real and meaningful effort by an organization to change its whole approach to business to make quality a guiding factor is everything the organization does. The major ingredients in TQM are discussed below[3-5].

1. Strategic commitment: The start point for TQM is a strategic commitment by the management. First the organizational culture must change to recognize that quality is not just an ideal but is instead an objective goal that must be pursued. Secondly, a decision to pursue the goal of quality carries with it some real costs – for expenditures such as new equipments and facilities. Thus, without a commitment from top management, quality improvement will prove to be just a slogan or gimmick, with little or no real change.
2. Employee involvement: Employee involvement is another critical ingredient in TQM. Virtually all successful quality enhancement programs involve making the person responsible for doing the job responsible for making sure it is done right. By definition, then employee involvement is critical component in improving quality.
3. Materials: Another important part of TQM is improving the quality of the materials that organization use.
4. Technology: New forms of technology are also useful in TQM programs. Investing in higher-grade machine capable of doing jobs more precisely and reliably often improves quality.
5. Method: Improved methods can improve product and service quality. Methods are operating systems used by the organization during the actual transformation during the actual transformation process.

MANAGEMENT TOOLS FOR PROCESS ANALYSIS, PLANNING AND DECISION MAKING:

The environmental aspects and impact must be characterized for each process, activity, product, or service is described. Objectives, targets will have to be linked to the quality policy. After the development of the total quality management, vision, mission, and value statements it is important to analyze the organization's processes and provide the information needed to develop activity specific policies, procedures, and work instruction to carry out the TQM. Popular decision making tools e. g. flowcharts, cause-and-effect diagram, brainstorming, histograms, SWOT (strength-weakness opportunities-threat) analysis, Pareto diagram etc may be applied planning, evaluation and continual improvement activities [3,4,6-9].

Cause-and-effect diagram:

The cause and effective or CE diagram (also known as Fish-Bone Diagram) come of a brainstorming session, wherein various causes are identified for an effect. For example, in any manufacturing process the various factors that can effect it can be grouped in so called 4 M's, viz. materials, men, machines and methods. Therefore, a variation in materials, machines, personnel and methods can add up to great deal of final product quality variation. Thus in any TQM effort which uses this tool to analyze problems in a manufacturing process, normally starts with these primary causes. Example: cost reduction analysis.

Brainstorming:

Putting the right group together and letting it brainstorm can have tremendous positive results, and there are many potential uses for this technique in the continual improvement program. Participants should be those people who are affected by the problem. Many quality programs use "quality circles" or "focus groups" to develop ideas for program development and improvement. These are similar in concept to brainstorming followed by analysis of data. Brainstorming can be used for selected problems or as part of the day-today activities.

FADE:

Another technique that can be used to build on the ideas generated during brainstorming is the FADE (Focus, Analyze, Develop, and Execute) process, which was popularized by the total quality management (TQM) movement. The participants focus on specific topics, analyze these topics, develop solutions, and execute those solutions. In this process, the information developed during brainstorming is organized and analyzed.

Pareto diagram:

An Italian economist, Velfredo Pareto, discovered a rule while studying distribution of income in 1897. Later management experts also applied the rule to organizations. Juran observed that the majority portion of quality problems are on account of a very few types of defects arising out of a relatively small number of causes. Therefore, if these vital few causes are looked into and controlled, then the quality problems are solved to a great extent. It has been found that in organizational problem analysis that, 80% of the problems are caused by 20% of all causes. Therefore by solving 20% of all causes about 80% of the problems can be solved. This rule has come to be known as 80/20 rule or 'vital few' and 'trivial many' principle. Experience shows that this is indeed that this is indeed so in various spheres of life.

The Pareto diagram depicts the following:

1. Number of percentage defectives for each source or cause.
2. Cumulative number or percentage defectives, and
3. Identification of causes which together account for specified percentage of defectives.

CONCLUSION

The pharmaceutical manufacturer assumes the major responsibility for the quality of his products. The professional, social and legal responsibilities that rest with the pharmaceutical manufacturers for the assurance of product quality are tremendous. It should be realized that no amount of dosage form testing and control can maintain and assure product quality unless good manufacturing practices (GMP) are implemented systematically and process control is practiced rigorously. It is only through well organized, adequately staffed accurately performed process and dosage form control before, during and after production that adequate quality assurance of the product can be achieved. Product quality must be build into and not merely tested in the product.

The manufacturer should be in a position,

a. to control the sources of product quality variation, namely materials, machines, methods and men.
b. to ensure the correct and most appropriate manufacturing and packaging practices.
c. to assure that the testing results are in compliance with the standards or specifications.
d. to assure product stability and to perform other activities related to product quality through a well-organized total quality assurance system.

For the total quality management system to function effectively, certain basic operational rules should be established and should always prevail. First, control decisions must be based solely on considerations of product quality. Second, the operation must adhere rigidly to the established standards or specifications as determined by systemic inspection, sampling and testing, and should constantly strive for improving the levels of the current standards or specifications. Third, the facilities, funds for personnel and environment necessary for personnel to perform their responsibilities effectively should be adequately provided. Last but not the least, the control decisions should be independent administratively, and they must not yield to or be overruled by, production or marketing under any circumstances. Because the control decision can involve the health of the consumer and the reputation of the pharmaceutical manufacturer, the climate necessary for making judicious decisions is essential. In times of major disagreements, the control decision should be subjected to review only at the highest level of management.

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