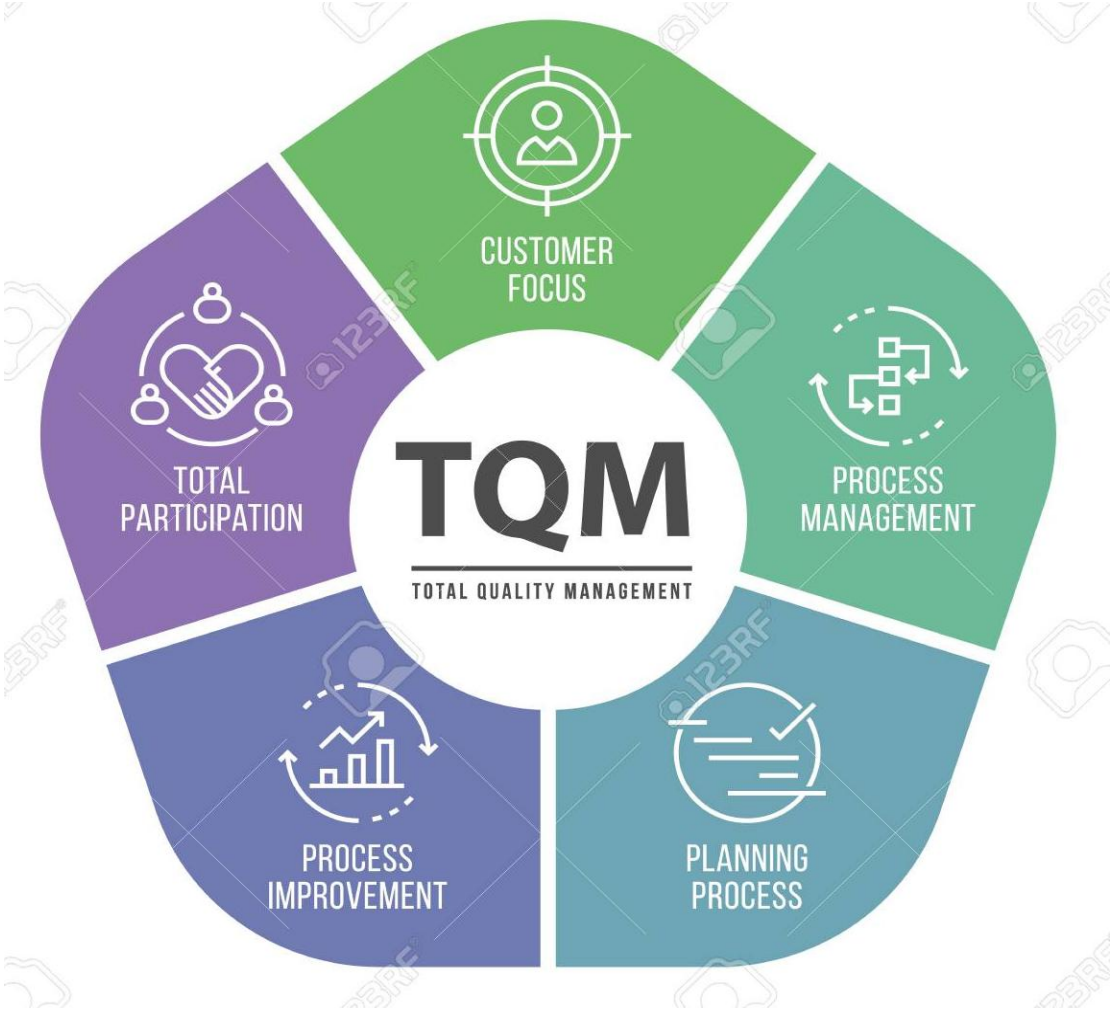
Pharmaceutical Analysis (3T3)

Unit -1 TOTAL QUALITY MANAGEMENT

1. Introduction



Total Quality Management (TQM) is a concept created by W. Edwards Deming. It was originally introduced in Japan after World War II to assist the Japanese in re-building their economy. The main focus of TQM was and is continuous quality improvement in the areas of product or service, employer-employee relations and consumer-business relations. Total Quality Management is a management approach that originated in the 1950s and has steadily become more popular since the early 1980s. 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 for the first time to eradicate defects waste from operations.

Total Quality Management is a method by which management and employees can become involved in the continuous improvement of the production of goods and services. It is a combination of quality and management tools aimed at increasing the business and reducing losses due to wasteful practices. Performance indicators; performance evaluation; evaluation of reference sources using precision and recall rations; cost benefit and cost effectiveness studies; user surveys electing opinions on library services all these make a part and parcel of quality studies using different mechanisms of assessment and methodologies.

2. Definitions of Total Quality Management

Definition of Quality

Defining quality is far from easy. Just try to find why one finds that a product is not of quality. Quality refers to grade of service, product, reliability, safety, consistency and consumer's perception. The notion of quality often subsumes a comparison between products. Product A is better than B and therefore has a higher quality. However, the word "better" is vague and different definitions can be used. Quality: means "degree of excellence"; implies "comparison", is not absolute. Quality – is to satisfy customers' requirement continually, where as Total Quality is to achieve quality at low cost. Broadly quality includes fitness for use, grade, degree of preference, degree of excellence and conformity to requirements. According to British Standard BS 7850, quality is defined as "Quality is concerned with meeting the wants and need of customers".

Quality Planning

Quality planning is the pre determined activities in order to achieve conformation to the requirements. Many organizations are finding that strategic quality plans and business plans are inseparable. The quality planning procedure given by Juran, has the following steps:

• Identify the customers

• Determine their needs

• Translate those needs into our language

• Develop a product that can respond to those needs

• Optimize the product features to meet our and customer needs

Quality Costs

All organizations make use of the concept of identifying the costs needed to carry out the various functions – product development, marketing, personnel, production etc., During the 1950's the concept of "Quality Cost" emerged. Different people assigned different meanings to the term. Some people equated quality cost with the cost of attaining quality; some people equated the

term with the extra incurred due to poor quality. But, the widely accepted thing is “Quality cost is the extra cost incurred due to poor or bad quality of the product or service”.

Categories of Quality Cost

Many companies summarize quality costs into four broad categories. They are;

a) Internal failure costs - The cost associated with defects that are found prior to transfer of the product to the customer.

b) External failure costs - The cost associated with defects that are found after product is shipped to the customer.

c) Appraisal costs - The cost incurred in determining the degree of conformance to quality requirement.

d) Prevention costs - The cost incurred in keeping failure and appraisal costs to a minimum. Sometimes we can also include the hidden costs i.e. implicit costs.

3. Total Quality Management

ISO defined TQM as “A management approach of an organization centered on quality, based on participation of all its members and aiming at long term benefits to all members of the organization and society.” TQM is "a system of continuous improvement employing participative management and centered on the needs of customers". TQM is the application of a number of activities with perfect synergy.

The various important elements of TQM are:

• Customer-driven quality;

• Top management leadership and commitment;

• Continuous improvement;

• Fast response;

• Actions based on facts

• Employee participation;

Four-level model in TQM

In his study of total quality management in managing quality, Dale outlines a four-level model of the evolution of quality management. In addition to the framework it proposes, clear definitions of quality terms are also provided.

Level 1. Inspection: measure the characteristics of a product and compare them with its specifications; the goal here is the fitness of standards. This is the passive "Inspecting" attitude. Level 2. Quality Control: inspection performed by the workers themselves with a feedback loop to the production line; here we avoid the "inspector" effect and allow some learning to take place.

Level 3. Quality Assurance: set of (implemented) predefined and systematic activities necessary to give confidence in the process quality; one step further. Quality procedures are designed and planned as a whole to ensure that no bad products be delivered. We do not just rely on everybody's work and control. This introduces the notion of a coherent set of quality procedures/tests. The given confidence (in the definition of QA) is important both for the producer and for the customer.

Level 4. Total Quality Management: centered on quality and based on the participation of everybody which aims at the customer satisfaction and at the improvement of the company's personnel, of the company and of the society. The ultimate step in TQM is a quality assurance plan is operational but the management; the workers and the customers continuously interact to review/improve this plan.

4. Components of TQM

The seven identified components of TQM are: Leadership, policy and strategy, training and development, staff management, teamwork, resources and processes. These components of TQM are fundamental to the basic principles of TQM, propounded by the quality gurus and available in all established TQM literature

Benefits of TQM

Customer satisfaction oriented benefits of TQM are;

1. Improvement in product quality

2. Improvement in product design

3. Improvement in production flow

4. Improvement in employee morale and quality consciousness

5. Improvement in product service

6. Improvement in market place acceptance

Economic improvement oriented benefits of TQM are,

1. Reduction in operating costs

2. Reduction in operating losses

3. Reduction in field service costs

4. Reduction in liability exposure

Concept of continuous improvement by TQM

TQM is mainly concerned with continuous improvement in all work, from high level strategic planning and decision-making, to detailed execution of work elements on the shop floor. It stems from the belief that mistakes can be avoided and defects can be prevented. It leads to continuously improving results, in all aspects of work, as a result of continuously improving capabilities, people, processes and technology. Continuous improvement must deal not only with the improving results, but more importantly with improving capabilities to produce better results in the future. The five major areas of focus for capability improvement are; demand generation, supply generation, technology, operations and people capability.

A central principle of TQM is that mistakes may be made by people, but most of them are caused, or at least permitted, by faulty systems and processes. This means that the root cause of such mistakes can be identified and eliminated and repetition can be prevented by changing the process (Gilbert, 1992). There are three major mechanisms of prevention: 1. Preventing mistakes (defects) from occurring (mistake-proofing or pokayoke). 2. Where mistakes can't be absolutely prevented, detecting them early to prevent them being passed down the value-added chain (inspection at source or by the next operation). 3. Where mistakes recur, stopping production until the process can be corrected, to prevent the production of more defects. (Stop in time).

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 for 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.

The very primary step in implementing TQM is to accesses the organization's 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 track 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.

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 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.