

TOTAL QUALITY MANAGEMENT

BP 606T (VI sem)

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Introduction



Total - made up of the whole

Quality - degree of excellence a product or service provides

Management - act, art or manner of planning, controlling, directing,....

Therefore, TQM is the art of managing the whole to achieve excellence.

The concept of TQM

- Produce quality work the first time.
- Focus on the customer.
- Have a strategic approach to improvement.
- Improve continuously.
- Encourage mutual respect and teamwork.

Various Definitions

- > Total quality management (TQM) has been defined as an integrated organizational effort designed to improve quality at every level.
- > The process to produce a perfect product by a series of measures require an organized effort by the entire company to prevent or eliminate errors at every stage in production is called total quality management.
- > According to international organization for standards defined tqm as, “TQM is a management approach for an organization, centered on quality, based on the participation of all its members and aiming at long-term success through customer satisfaction and benefits to all members of the organization and to the society.

Characteristics of TQM

- > Committed management.
- > Adopting and communicating about total quality management.
- > Closer customer relations.
- > Closer provider relations.
- > Benchmarking.
- > Increased training.
- > Open organization
- > Employee empowerment.
- > Flexible production.
- > Process improvements.
- > Process measuring

Traditional approach and TQM

| Quality element | Previous state | TQM |
|-----------------|------------------------------------|---|
| Definition | Product-oriented | Customer-oriented |
| Priorities | Second to service and cost | First among equals of service and cost |
| Decisions | Short-term | Long-term |
| Emphasis | Detection | Prevention |
| Errors | Operations | System |
| Responsibility | Quality Control | Everyone |
| Problem solving | Managers | Teams |
| Manager's role | Plan, assign, control, and enforce | Delegate, coach, facilitate, and mentor |

The three aspects of TQM

Counting

Tools, techniques, and training in their use for analyzing, understanding, and solving quality problems

Customers

Quality for the customer as a driving force and central concern.

Culture

Shared values and beliefs, expressed by leaders, that define and support quality.

Principles of tqm

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

The key elements of the TQM

- > Focus on the customer.
- > Employee involvement
- > Continuous improvement



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.



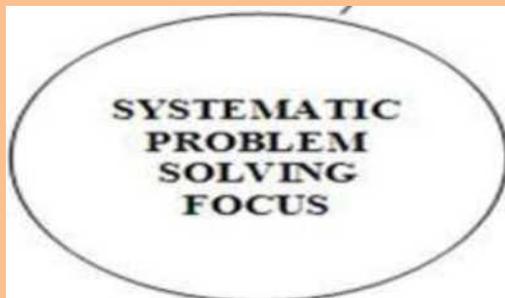
Employee Involvement

- 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.

Continuous improvement



Continuous improvement



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.
- TQM is the management process used to make continuous improvements to all functions.
- TQM represents an ongoing, continuous commitment to improvement.

Continuous Process Improvement.

- View all work as process - production and business.
- Process - purchasing, design, invoicing, etc.
- Inputs - process - outputs.
- Process improvement - increased customer satisfaction.
 - Improvement - 5 ways:
 - Reduce resources, reduce errors, meet expectations of downstream customers, make process safer, make process more satisfying to the person doing

THE TQM SYSTEM

Objective



Principles

| | | | |
|-----------------|--|--------------------|--------------------|
| <i>Customer</i> | | <i>Process</i> | <i>Total</i> |
| | | <i>Improvement</i> | <i>Involvement</i> |
| <i>Focus</i> | | | |

Elements

Leadership
Education and Training
Supportive structure
Communications
Reward and recognition
Measurement

BENEFITS OF TQM:

- Improved quality.
- Employee participation.
- Team work.
- Working relationships.
- Customer satisfaction.
- Employee satisfaction.
- Productivity.
- Communication.
- Profitability.
- Market share.

Importance of TQM in pharma industry

Handling:

- Containers should be opened carefully and subsequently resealed in an approved manner.
- Highly sensitizing material such as penicillins and cephalosporins should be handled in separate production areas.
- Highly active or toxic API (e.g. certain steroids, cytostatic substances) should be manufactured in a dedicated area and using dedicated equipment.
- Pure and final API should be handled in an environment giving adequate protection against contamination.

Storage:

- Secure storage facilities should be designated for use to prevent damage or deterioration of materials.
- These should be kept clean and tidy and subject to appropriate pest control measures.
- Environmental conditions should be recorded.
- The condition of stored material should be assessed at appropriate intervals.
- Storage conditions for api should be based upon stability studies taking into account time, temperature, humidity, light etc



Packaging:

- Labelling and packaging processes should be defined and controlled to ensure that correct packaging materials are used correctly and other specified requirements are met.
- Printed labels should be securely stored to avoid mix-ups arising.
- Marking and labelling should be legible and durable, provide sufficient information, for accurate identification and indicate, if appropriate, required storage conditions, retest and/or expiry date.

Facilities and equipment:

- The location, design, and construction of buildings should be suitable for the type and stage of manufacture involved, protecting the product from contamination (including cross-contamination) and protecting operators and the environment from the product.
- Equipment surfaces in contact with materials used in api manufacture should be non-reactive.

Sterile area

- Personnel suffering from an infectious disease or having open lesions on the exposed surface of the body should avoid activities which could compromise the quality of API.
- Smoking, eating, drinking, chewing and storage of food should be restricted to designated areas separated from production or control areas.



Labelling

- Each container should be identified by an appropriate label, showing at least the product identification and the assigned batch code, or any other easily understandable combination of both.
- Containers for external distribution may require additional labels.

Computerised systems

- . Computer systems should be designed and operated to prevent unauthorised entries or changes to the programme.
- In the case of manual entry of quality critical data there should be a second independent check to verify accuracy of the initial entry.
- A back-up system should be provided of all quality critical data.

Advantages of tqm



- Improves reputation- faults and problems are spotted and sorted quicker.
- Higher employee morale- workers motivated by extra responsibility ,team work and involvement indecisions of tqm.
- Lower cost.
- Decrease waste as fewer defective products and no need for separate.

Disadvantages of tqm



- Initial introduction cost.
- Benefits may not be seen for several years.
- Workers may be resistant to change.

A model for organization management.



Models of tqm



BENEFITS OF TOTAL QUALITY MANAGEMENT

- Financial benefits include lower costs, higher returns on sales and investment, and the ability to charge higher rather than competitive prices.
- Improved access to global markets, higher customer retention levels, less
- Time required to develop new innovations, and a reputation as a quality firm.
- Total quality management (tqm) is one such approach that seeks to improve quality and
- Performance which will meet or exceed customer expectations.



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 realized 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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