

## Review Article

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# Total Quality Management: The Need of the Hour for Pharmaceutical Industry

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### ABSTRACT

Total quality management play major role starting from initial establishment of a pharmaceutical industry to safe guard the marketed drug. It controls the overall quality system chain of a pharmaceutical product, which is to be purchased and utilized by the public in need. TQM is not un-dimensional approach but is multifaceted in nature. Understanding these facts is essential to promote a successful quality improvement programmed. An integrated approach on all vital components of TQM is required to achieve the desired goal. TQM has been accepted by both service and manufacturing organization, globally as a systemic management approach to meet the competitive challenges. TQM redefines the quality with emphasis on top management commitment and customer satisfactions. Drastic reduction in materials wastage, average saving per year increased and financial losses were minimized, workers were motivated to keep and operate materials with care and prevent wastage, and good team relationship was built among the workman and management. TQM provides the linkage between productivity and quality. The focus of TQM is an Involvement of everyone in organization in continuous improvement, Commitment to satisfy the customers, Participation through teamwork, Commitment and leadership of top management.

**Key-words:** Total quality management (TQM)

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### **Introduction:**

Approaches to quality by Crosby, Feigenbaum and Ishikawa

In ISO 9000: 2000:

“Quality is defined as ‘the ability of a set of inherent characteristics of a product, system or process to fulfill requirements of customers and other interested parties’.

Crosby talks about ‘conformance to requirements’.

Feigenbaum emphasizes that quality is not an absolute as in ‘the best’ but relates to ‘best for the customer use and selling price’.

### **Quality is Relative in Nature:**

In literature, Quality is sometimes talked about as "what the customer wants". The customer is then defined as "internal" (someone who is within the area of process, the one who experiences whatever is done immediately when it is done) and "external" (someone who, typically, buys what is done or receives it as a final output). Customer wants products with zero defects which is practically not possible. But management can build up the quality of the products in each and every step rather than building at the last stage. If a product fulfills the customer's expectations, the customer will be pleased and consider that the product is of acceptable or even high quality.

If his or her expectations are not fulfilled, the customer will consider that the product is of low quality. This means that the quality of a product may be defined as “its ability to fulfill the customer's needs and expectations”. Main aim of TQM is that to fulfill customer requirements in all aspects and satisfying them with effectively and profitably. But the problem is that customer has never fully defined what is required.

### **Raising the concept of TQM:**

With advance in modern science and progress of mankind, people have come realize that quality is not what is stamped onto or put into the final product. It has to be built into the product right from the conception to marketing.

### **TOTAL QUALITY MANAGEMENT (TQM) Introduction:**

- TQM is relatively new concept of quality control. It is basically, a management function involving the direction of top management and co-ordination of all quality related activities throughout the company to achieve Zero defects and customer satisfaction.
- The topic is of contemporary interest to industrial pharmacist, community pharmacist and to all those who are conscious about quality.
- ✓ Since quality is a measure of the users satisfaction provided by the product, it should include –
  - Functional efficiency
  - Appearance
  - Ease of installation and operation
  - Safety
  - Reliability
  - Maintainability
  - Running and maintenance cost
- ✓ In this quality awareness begins at the very conception of the product and continues during the various stages of its development and manufacture and even its usage to provide feedback from the users which is so essential for quality improvement.
- ❖ Elements of TQM: Total quality is a description of culture, attitude and organization of a company that strives to provide customers product and services that satisfy their needs. Successful implementing TQM an organization must concentrate on 8 key elements are:
  1. Ethics
  2. Integrity
  3. Trust
  4. Training

5. Team work
6. Leadership
7. Recognitions
8. Communications

❖ Obstacles in implementing TQM

- ▶ Lack of a company-wide definition of quality
- ▶ Lack of a formalized strategic plan for change
- ▶ Lack of a customer focus
- ▶ Poor inter-organizational communication
- ▶ Lack of real employee empowerment
- ▶ Lack of employee trust in senior management
- ▶ View of the quality program as a quick fix
- ▶ Drive for short-term financial results
- Politics and turf issues.

❖ Pharmaceutical quality management system:

- Management responsibility
- Continual improvement of process performances and product quality.
- Continual improvement of the pharmaceutical quality system

● Management responsibility:

Management commitment  
Quality policy  
Quality planning  
Resources management  
Internal communication  
Management review

Management of outsourced activities and purchased material  
Management of change in product ownership

● Continual improvement of process performances and product quality:

Lifecycle stage goals  
Pharmaceutical quality system element

● Continual improvement of the pharmaceutical quality system

Management review of the pharmaceutical quality system  
Management of internal and external factors impacting the pharmaceutical

● Main function of the regulatory authority for medicines are: Registration of products Inspection and licensing for manufacture. Inspection and licensing for distributors. Post marketing surveillance .Regulation of statements that can be made for commercial promotion of the product. Authorization of clinical trial

- ❖ Role of regulatory bodies in quality management: Regulatory bodies do the investigation of deviations in deviation system must required all deviation to be classified or ranked based on risk to the patient .Risk assessment must be documented .For those considered more serious, an effective impact assessment and root cause analysis must be performed and documented .Appropriate corrections should be implemented and corrective action should be taken to ensure the problem does not reoccur. Internal audits should look for evidence of recurrence and deviations should be trended for the same purpose Regulatory expectation are that senior management should ensure that the quality system includes all the necessary element/systems that drive continuous improvement and risk based thinking and should review them on a formal regular basis at a quality review meeting. Every company should have a documented approach to minimize contamination , including a requirement to raise a change request to introduce a new product or molecule, resulting in an impact and risk assessment.

□ Historical Philosophies of Quality:

- Quality Gurus

'Individuals who have been identified as making a significant contribution to improving the quality of goods and services'

- Walter A. Shewhart
- W. Edwards Deming
- Joseph M. Juran
- Armand Feigenbaum
- Philip Crosby
- Genichi Taguchi
- Kaoru Ishikawa

Commonalities of Themes of Quality Gurus

- ✓ Inspection is never the answer to quality improvement, nor is "policing".
- ✓ Involvement of leadership and top management is essential to the necessary culture of commitment to quality
- ✓ A program for quality requires organization-wide efforts and long term commitment, accompanied by the necessary investment in training
- ✓ Quality is first and schedules are second

 **PHILIP CROSBY:**

Quality is defined as conformance to requirements, neither as 'goodness' nor 'Elegance'.

- There is no such thing as a quality problem.
- It is always cheaper to do it right first time.
- The only performance measurement is the cost of quality.
- The only performance standard is zero defects.

Crosby's five absolutes of quality:

1. Quality is defined as conformance to requirements, not as 'goodness' or 'elegance':
2. There is no such thing as a quality problem.
3. It is always cheaper to do it right first time.
4. The only performance measurement is the cost of quality.
5. The only performance standard is zero defects

Summarizing Crosby's perspective on quality, there appear to be three essential strands:

- A belief in quantification
- Management leadership
- Prevention rather than cure.

Quality is then considered by Crosby to be an inherent characteristic of the product not an added extra.

He considers that the workers must not be blamed for error, but rather, that management should take the lead and that the workers will then follow.

Crosby suggests that 80 per cent of quality problems are within the control of management

Methods for quality improvement:-

Step 1 *Establish management commitment*

Step 2 *Form quality improvement teams*

Step 3 *Establish quality measurements*

Step 4 *Evaluate the cost of quality*

Step 5. *Raise quality awareness*

Step 6 *Take actions to correct problems*

Step 7 *Zero defects planning*

Step 8 *Train supervisors and managers*

Step 9 *Hold a 'Zero Defects' day* to establish the attitude and expectation within the company.

Step 10 *Encourage the setting of goals* for improvement.

Step 11 *Obstacle reporting*

Step 12 *Recognition for contributors*

Step 13 *Establish Quality Councils*

Step 14 *Do it all over again*

### **ARMAND V. FEIGENBOUM**

Quality is simply a way of managing a business organization.

Four steps to quality: Armand V. Feigenbaum

Step 1 Set quality standards.

Step 2 Appraise conformance to standards.

Step 3 Act when standards are not met.

Step 4 Plan to make improvements.

✓ Advantage of Feigenbaum theory:

Feigenbaum's approach has undoubtedly been successful and has been adopted in whole, or in part, by a number of organisations.

- Emphasis on the importance of management;
- Socio-technical systems thinking is taken into account; participation is promoted

✓ weaknesses are:

- The work is systemic but not complementary;
- The breadth of management theory is recognised but not unified;
- The political or coercive context is not addressed.

❖ Feigenbaum's 10 benchmarks for total quality success:

1 Quality is a company-wide process.

2 Quality is what the customer says it is.

3 Quality and cost are a sum, not a difference.

4 Quality requires both individual and team zealotry.

5 Quality is a way of managing.

6 Quality and innovation are mutually dependent.

7 Quality is an ethic.

8 Quality requires continuous improvement.

9 Quality is the most cost-effective, least capital-intensive route to productivity.

10 Quality is implemented with a total system connected with customers and suppliers.

### **KAORO ISHIKAWA:**

He is a 'Father of Quality Circles' and as a founder of the Japanese quality movement

His approaches include:-

1. An atmosphere where employees are continuously looking to resolve problems;
2. Greater commercial awareness;
3. a change of shop floor attitude in aiming for ever increasing goals.

Methods:

Quality circle is a voluntary group of employees who work on similar tasks or share an area of responsibility. The group agrees to meet on a regular basis to discuss & solve problems related to work. The team operates on the principle that employee participation in decision-making and problem solving improves the quality of work.

1) The number of members range from 3-12 people.

2) The focus is on specific issues to resolve problems.

3) The team generally meets once a week to analyze work related problems and proposes solutions to Management and where possible implements those solutions.

4) Members also tend to generate a mutual respect and trust as they work on solutions, which is conducive for collaborating as a team.

- How Quality Circles Works.

The quality circle works with Volunteers who have Set Rules and Priorities and they make decisions made by Consensus and they use organized approaches to Problem-Solving. In the quality circles all the members of a circle need to be trained on the required skills and be empowered for decision making. The quality circle should have the support of Senior Management.

- ❖ The challenges in sustaining the Quality Circles

The major challenges in sustaining the quality circles are;

1. Lack of understanding what Quality Circles may cause management to be reluctant to initiate circles, act upon circle suggestions; or being eager for quick solutions, may implement these suggestions too early
2. Lack of clear purpose or direction; without having a clear purpose it is difficult to be a productive team.
3. Lack of volunteers; under circumstances like this, the employee at times is reluctant to be part of the team and the team loses focus
4. Lack of support from Management and loss of interest in the project that the circle is working on is also a hindrance in the success of the circle &
5. Without empowerment and support of the management staff, circles will not have the resources provided to them to be successful.

Formation of Quality Circle

The following basic elements constitute the structure of the quality circle:

- i) Top Management
- ii) Steering committee
- iii) Co-coordinator
- iv) Facilitator
- v) Leader
- vi) Members
- vii) Non-members

TOOL 1	Pareto charts	Used to identify the principal causes of problems.
TOOL 2	Ishikawa/fishbone diagrams	Charts of cause and effect in processes.
TOOL 3	Stratification	Layer charts which place each set of data successively on top of the previous one.
TOOL 4	Check sheets	To provide a record of quality
TOOL 5	Histograms	Graphs used to display frequency of various ranges of values of a quality.
TOOL 6	Scatter graphs	Used to help determine whether there is a correlation between two factors.
TOOL 7	Control charts	Used as a device in statistical Process Control.

Seven tools of quality control:kaoru ishikawa

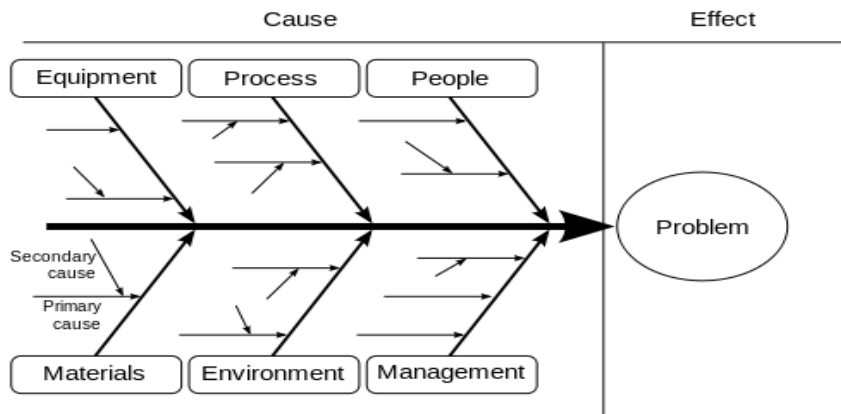
- ❖ Cause and effect diagram

The cause and effect diagram (also known as the Ishikawa or fishbone diagram) is used to display all the possible causes of a chosen problem – the effect. This helps people to get an overview of the full picture, before selecting specific areas to investigate further.

The effect is written in a box on the right-hand side of the page or flip-chart (the head of the fish) and the possible causes are listed on the left. To help clarify the situation, the causes are organized into a number of categories (the structure of the body). The categories that are chosen will depend on the problem being

evaluated. Causes are generated either by brainstorming or by some kind of pre-construction activities, such as check-sheet sampling. Each cause may then be further broken down if this is found to be useful.

## Fishbone Diagram



Categories of Causes

### The 6 M's

- Machine, Method, Materials, Maintenance, Man and Mother Nature (Environment) (recommended for the manufacturing industry)

### The 8 P's

- Price, Promotion, People, Processes, Place/Plant, Policies, Procedures, and Product (or Service) (recommended for the administration and service industries)

### The 4 S's

- Surroundings, Suppliers, Systems, Skills (recommended for the service industry)

- ✓ Fifteen effects of company-wide quality control: Kaoru Ishikawa

Effect 1 Product quality is improved and becomes uniform. Defects are reduced.

Effect 2 Reliability of goods is improved.

Effect 3 Cost is reduced.

Effect 4 Quantity of production is increased, and it becomes possible to make rational production schedules.

Effect 5 Wasteful work and rework are reduced.

Effect 6 Technique is established and improved.

Effect 7 Expenses for inspection and testing are reduced.

Effect 8 Contracts between vendor and vendee are rationalised.

Effect 9 the sales market is enlarged.

Effect 10 Better relationships are established between departments.

Effect 11 False data and reports are reduced.

Effect 12 Discussions are carried out more freely and democratically.

Effect 13 Meetings are operated more smoothly.

Effect 14 Repairs and installations of equipment and facilities are done more rationally.

Effect 15 Human relations are improved.

- ✓ Successes and failures:



Ishikawa's world-wide status and the widespread acceptance of his ideas suggest that his approach has met with considerable success. That he is best known for the fishbone diagram. Similarly, that quality circles have been successful cannot be doubted.

✓ Advantages of Ishikawa's approaches:

- Emphasis on participation;
- variety of quantitative and qualitative methods;
- a whole system view;

The main weaknesses can be viewed as:

- Fishbone diagrams are systematic but not systemic;
- QCC's depend upon management support;
- There is a failure to address coercive contexts, fishbone diagram is limited in its use.
- The second weakness faced when management is not prepared to listen to the ideas emerging from quality circles.
- In this case, the organization is probably facing the third weakness, that the approach would struggle in a political or coercive context.

### Conclusion:

With the growing demand for quality products, many initiatives were framed by organizations to assure consistency in what they produce. The nation are orienting their quality management strategies and systems to meet the requirements of operating environment though the primary focus remain the same, that is total customer satisfaction..*Quality is simply a way of managing a business organization and also give the word total quality control.*

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