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Total Quality Management in Pharmaceuticals: A Review

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Abstract: Implementation of an effective quality assurance policy is the most important goal of pharmaceutical industry. The concept of quality assurance and quality control together develops towards assuring the quality, safety and efficacy of pharmaceutical products. Thus, quality is critically important ingredient to organizational success today, which can be achieved by total quality management (TQM), an organizational approach that focuses on quality as an over arching goal, aimed at the prevention of defects rather than detection of defects. It is a philosophy and practice of integrative quality management system adopted worldwide in pharmaceutical industries along with other regulatory requirements. The TQM perspective views quality as the pivotal purpose of the organization. Present review attempts to furnish a wide overview of the TQM concept and the management means leading to quality improvement of pharmaceuticals.

Key words: Quality assurance, total quality control, total quality management (TQM), pharmaceutical.

INTRODUCTION

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 poor qualities of medicines are not only a health hazard, but also a waste of money for both government and individual consumers. Therefore, the maintenance of quality with continuous improvement in facilities is very important in pharmaceutical industries. 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.

The concept of total quality control refers to the process to produce a perfect product by a series of measures requiring an organized effort by the entire company to prevent or eliminate errors at every stage in production. Although the responsibilities for assuring product quality belong primarily to quality assurance personnel, it involves many department and disciplines within a pharmaceutical company. To be effective, it must be supported by a team effort. Quality must be built into a pharmaceutical product during product and process design and it is influenced by the physical plant design, space, ventilation, cleanliness and sanitation during routine production[1].

The assurance of quality of the product depends on more than just proper sampling and adequate testing of various components and finished dosage forms (products). Prime responsibility of maintaining the product quality during production rests with the manufacturing department. Quality assurance personnel must establish control or check points to monitor the quality of the product as it is processed and up to completion of manufacturing. This begins with raw materials and component testing and includes in-process packaging, labeling and finished product testing as well as batch auditing and stability monitoring.

Quality assurance policy, therefore, become the most important goal of pharmaceutical industry. 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[1,2].

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 over arching 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[3].

QUALITY

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. 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. The code defines as 'quality therefore is the totality of features and characteristics of a product/service that bears on its ability to satisfy given needs'[2].

If we are selecting a tablet for purchasing, we shall compare the different brands of that particular tablet on the basis of their therapeutic efficacy and side-effects, colour and odours. Thus a customer/user of a product make a comparison of features or attributes of the product and also the absence of deficiency in it, while comparing the quality.

Thus the quality, for a product or service, has two aspects, both of which together make for an appropriate definition of the term. The first relates to the features and attributes of the product or service. These ensure that the product or the services meets the needs of the user. The second aspect concerns the absence of deficiencies in the product.

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.

HISTORICAL OVERVIEW OF QUALITY MANAGEMENT

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. Many of the tools and techniques that were used to identify quality problems and take corrective action date back decades earlier. 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. His book "Economic Control of Quality", published in 1931, is still considered a classic. Joseph M. Juran was a statistician who in 1940s introduced the concept of "Pareto analysis", which argues that 80 % of all quality problems may be traced to a relatively small number of causes. Phillip Crosby spent his entire career at International Telephone and Telegraph. While there, Crosby documented the enormous costs of having to fix something that was not done right the first time. His ideas were later published in the business best seller "Quality is Free". Arnand V. Feigenbaum developed the concept the concept of "total quality control" in the 1940s, which argues for an integrated quality improvement effort across all functional areas (e.g. purchasing, finance, marketing) and not only in production and manufacturing. These ideas were later published in the book, "Total Quality Control".

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. Quality control involves detection and elimination of components and final products, which are not standard. It is an after the event process. 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].

The quality improvement movement got its momentum in Japan in the decade of '60s during the re-construction of its post second world war economy. Two Americans quality gurus, Deming and Juran initiated the movement and the concepts of Quality Assurance followed by total quality control (TQC) came in. Quality assurance is concerned with the first place and is before and during the event process. The aim in the words of Crosby is "zero defects". The responsibility lies with the work force, usually working in teams or cells. TQC has been described as "a management framework to ensure continuing excellence". Here, 'Total' indicates that everything and everyone in the organization is involved in pursuit of purity. It was also called as company wide quality control (CWQC).

USA facing the competition from the resurgent Japanese economy, during '80s, became conscious of quality and adopted the approach and called it total quality service, strategic quality management, quality initiative, quality first are some of the titles for TQM. An educational institution may adopt the title as 'student first' or 'institutional improvement programme' or any other title as they feel fit.

TOTAL QUALITY MANAGEMENT

It would be fair to say that the idea of TQM is a bit like idea of 'God', depending on which sect one belongs to. Different experts have attempted various definitions from time to time. It may be defined as- "It is continuously meeting agreed customer requirements at the lowest cost by realizing the potential of all employees".

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.
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.

TQM ACCORDING TO QUALITY GURUS

Background: In the field of quality there are quite a few names who actually introduced original concepts about quality since the early part of the lost century. The first to give quality and quality control a thrust was Dr. W. A. Shewhart who was described as 'as the man who discovered quality'. The most crucial breakthrough in modern quality movement came in 1931 with the publication of Shewhart's 'economic control of quality of manufactured products'. He was the first to have recognized the fact that 'variability was a part of industrial life and it could be understood and managed using principles of probability and statistics'. He gave quality movement a theoretical base when he defined the problem of managing quality as one of differentiating between acceptable variations (common causes or chance causes) and unacceptable variation due to special causes (assignable causes). He later developed what is known as the capability over a period of time. After Shewhart the mantel of development of the concept of quality fell on another stalwart Dr. W. Edwards Deming who was considered to be Shewhart's disciple[4,5-7].

W. Edwards Deming: Dr. Deming was basically a physicist and obtained a Ph.D. in mathematical physics. However he devoted the greater part of his illustrious life to the cause of quality. He realized that in regard to stability and variations of industrial processes the special causes (assignable causes) amounted to only 15 % of all causes and may be controlled by the work force. The rest 85% of causes could be dealt with by the management! Among his many contributions is the famous Deming Wheel which however he developed on the idea of his mentor Dr. Shewhart. Dr. Deming visited Japan in 1946 and again in 1948 as a representative of the US war Dept. however in 1950 he was invited by JUSE (Union of Japanese Scientist and Engineers) to deliver series of lectures on importance quality to the executives of the Japanese industries. This proved to be hugely beneficial to the Japanese industries in the subsequent years in its effort to become world leaders in quality – the rest is history. Amongst his many pioneering contribution his 14-point achieving organizational excellence is the best. Deming's fourteen points for quality improvement:

1. Constancy of purpose for continual improvement of product and service.
2. The new philosophy for economic stability.
3. Cease dependence on inspection to achieve quality.
4. End the practice of 'lowest tender' contracts.
5. Improve constantly and for ever every process of production and service.
6. Institute training on the job.
7. Institute modern methods of supervision and leadership.
8. Drive out fear.
9. Break down barriers between departments and individuals.
10. Eliminate use of slogans, posters and exhortation.
11. Eliminate arbitrary numerical targets/quotas.
12. Permit the workers right to pride of workmanship.
13. Encourage vigorous program of education/retraining.
14. Define top management's commitment to ever improving quality and productivity.

Joseph Juran: Another famous management consultant Dr. Joseph Juran also visited Japan in the early 1950s. Like Deming he delivered a series of lectures on quality management during 1954-55 to the Japanese top and middle level managers. He preached that quality begins at the stage of designing and ends after satisfactory services are provided to the customers. His famous definition for quality is 'fitness for use' which is jargon free and understood by everybody. He recommends a set of four important stages as:

- Establish specific goals to be reached (identification of needs to done, focus on specific project etc)
- Establish plan for reaching goals (development of structured process to achieve this)
- Assign clear responsibility for reaching goals
- Give rewards/awards on the basis of result achieved (development of feedback system, utilization of lessons learned from feedbacks etc).

Quality achievement, according to Juran, is possible through various initiatives that are the basis of his famous quality trilogy the main components of which are:

- Quality planning
- Quality control and
- Quality improvement

For the purpose of understanding the initiatives under the above three categories may be enlisted as follows:

- Build awareness of the need and given an opportunity for improvement
- Set goals for improvements
- Organize to teach the goals (establish a quality council, identify problems, select project, appoint teams, designate facilitators)
- Provide training
- Carry out projects to solve problems
- Report progress
- Give recognition
- Communicate results

- Keep score
- Maintain momentum by making annual improvement part of the regular systems and processes of the company.

Philip B. Crosby: Philip B. Crosby, again an American, is another internationally acclaimed quality guru. He is said to have done more than any other gurus to awaken the western management from its slumber and made them recognize the need of quality improvement for survival in the modern business world. He professed the idea that quality is a never ending journey and has to be pursued always. The essence of Crosby's teaching is contained in what he calls the "four absolutes of quality".

- First absolute: The definition of quality is conformance to requirement and not goodness.
- Second absolute: The system of quality is prevention and not appraised.
- Third absolute: The performance standard is zero defects.
- Fourth absolute: Measurement of quality is the price of non-conformance to requirement, not quality indices.

Based on these premises Crosby has developed a 14-step methodology which is presented below:

1. Management commitment: Clarify and demonstrate management's commitment to quality.
2. Quality improvement team: Guide the quality improvement programme.
3. Quality measurement: Display current and potential non-conformance problems in a manner that permits objective evaluation and corrective action.
4. Cost of quality: Define the ingredients of the cost of quality and explain its use as a management tool.
5. Quality awareness: Develop awareness about quality throughout the company towards the conformance of the product or service through effective communication channels.
6. Corrective action: Provide a systematic method of resolving forever the problem that is identified through previous action steps.
7. Zero defects planning: Examine the various activities that must be conducted in preparation for formally launching the zero defects (ZD) programmed.
8. Employee education: Define the type of training that the employees need in order to actively carry out their part of the quality improvement programme. Employee education process, according to Juran, comprises the following dimensions:
    - Comprehension
    - Commitment
    - Competence
    - Communication
    - Correction
    - Continuance
9. Zero defects day: Mark a day in the year as zero defects day. An event that will let all employees realize, through a personal experience, that there has been a change.
10. Goal setting: Set targets-turn pledges and commitments into action by encouraging individuals to establish improvement goals for themselves and their groups.
11. Error-cause removal: Give the individual employee a method of communicating to the management, the situations that make it difficult for them to meet the target and improve. It focuses on permanent removal of common causes of errors.
12. Recognition: Appreciate those who participate.
13. Quality councils: Bring together all quality professionals for planned communication on a regular basis.
14. Do it over again: Emphasize that the quality improvement is a never ending journey.

Armand Feigenbaum: Feigenbaum developed the concept of total quality control (TQC). He advocated a total approach to quality, involving everybody in any process and manufacturing or not. He emphasized on preventive maintenance as opposed to fire fighting. According to him quality is a way of managing business with a focus on customer requirements and with the understanding (as to what is said and done) and involvement. His concept of TQC encompasses all activities of organization – not the manufacturing activities alone. One of his important contributions has been that of cost of quality in which three categories are recognized such as:

- Appraisal costs (costs associated with discovery of failure e.g. inspection, audits etc)
- Failure costs (costs associated with failure e.g. fire fighting, scrap, rework etc) and
- Preventive costs (costs associated with preventive measures taken)

Genichi Taguchi: Dr. Genichi Taguchi one of the best known Japanese quality experts, four times recipient of the coveted Deming prize, developed techniques of industrial optimization. His revolutionary concept of quality as the loss imparted by the producer to the society from the time the product is shipped. Taguchi's approach focused on a statistical method that zeros in rapidly on the variations in a product that distinguish the bad parts from good. He calls it the concept of robust design. His contributions have acquired the title of Taguchi methods. In a nutshell Taguchi's 8-point approach towards quality may be listed as follows:

- Identify the main function, side effects and failure.

- Identify noise factors and testing conditions for evaluating quality loss.
- Identify the quality characteristics to be observed and the objective function to be optimized.
- Identify the control factors and define the data analysis procedure.
- Conduct the matrix experiment and define the data analysis procedure.
- Analyze the data, determine optimum levels for the control factors, and predict performance under these levels.
- Conduct the verification experiment and plan future action.

A manager must master 5 key competencies to succeed in a TQM organization:

- Developing relationships of openness and trust.
- Building collaboration and teamwork.
- Managing by fact.
- Supporting results through recognition and rewards.
- Creating a learning and continuously improving organization.

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 (Fig. 1). 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.

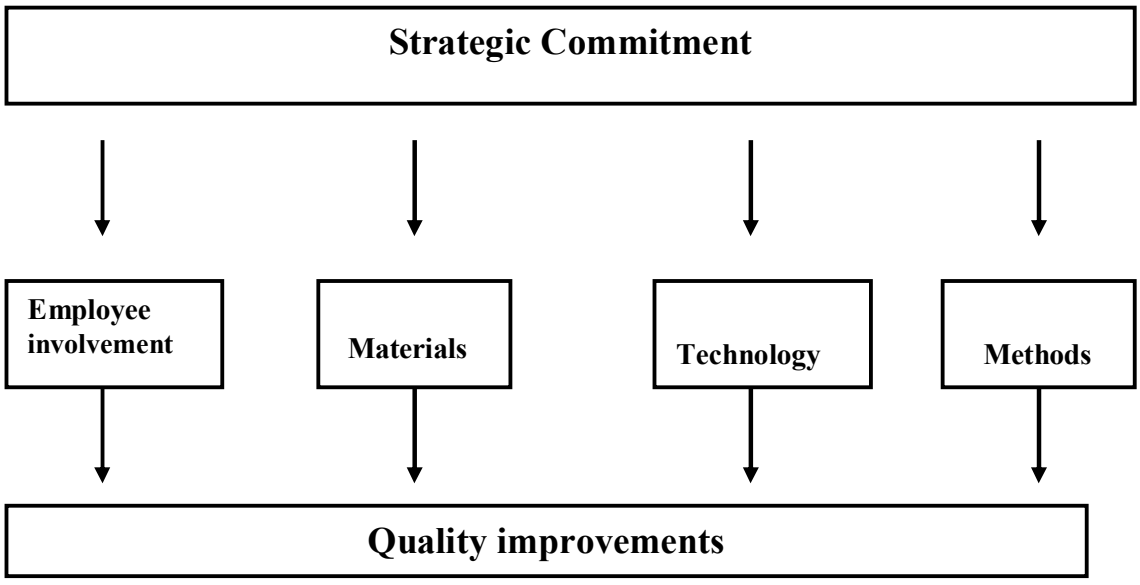


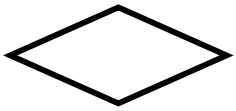
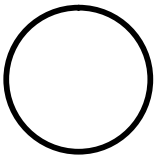
Fig. 1: Strategic commitment scheme.

MANAGEMENT TOOLS FOR PROCESS ANALYSIS, PLANNING AND DECISION MAKING

After the development of the TQM, 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. The environmental aspects and impact must be characterized for each process, activity, product, or service is described. This requires a thorough analysis of all the processes. Objectives, targets will have to be linked to the quality policy. 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].

Flowcharts: A flowchart is a diagram that uses connecting lines and a set of symbols to show the steps from beginning to end of an activity or procedure. Some commonly used symbols are shown in Table 1.

Table 1. Flowchart symbols.

	**Process**	Represents any type of process or activity such as writing a memo, purchasing equipment, or interviewing a job candidate.
	**Alternate process**	Represents an alternate type of process, such as external (versus internal) or static (versus variable). Although popular, this shape is not an ISO-standard or ANSI-standard shape.
	**Decision**	Indicates a point at which a decision must be made. Generally, two flow lines point and one out of the bottom and one out of the side. Each line will be marked with a decision option, such as "yes" & "no" or "false". These lines also can show branch options such as "Make" versus "Buy".
	**Input/output**	Represent the information that goes into or comes out a process. Examples of input are orders and inquiries. Examples of outputs are reports and products.
	**Document**	Represents an activity recorded in a document, such as a file or printed report.
	**Connector**	Links a shape to another point in the flowchart without using a line. A letter or number elsewhere in the circle corresponding letter or number elsewhere in the chart. It is also used to connect multiple lines at one point.
	**Terminal**	Indicates the start or end of a process. The beginning terminal shape generally is labeled "start" or "begin". The ending terminal shape is labeled "stop" or "end"

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. The resulting diagram shows pictorially the relationship between the identified causes and effect being looked into. 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 (Fig. 2).

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. 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. Participants should be those people who are affected by the problem.

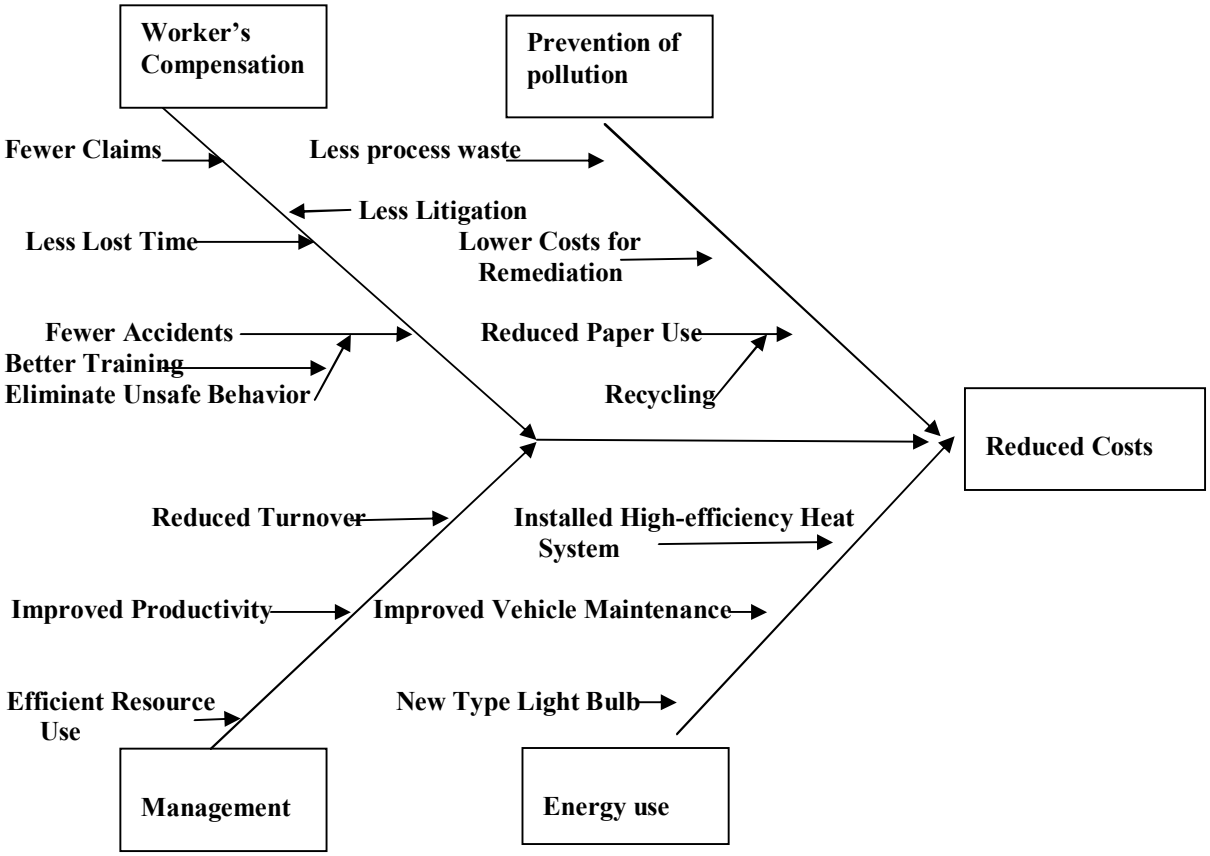


Fig. 2: Cause and effect diagram for cost reduction analysis.

Table 2. SWOT analysis.

Strength	Weakness	Opportunities	Threats
Location	Internal Dissention	Leadership improvement	Foreign competition
Market Position	New Leadership	New Markets	Market Swings
Skilled Staff	Turnover in key position	Possible new products	Possible leveraged buyout
Available capital	Regulatory compliance problems	EMS development	New competition
Developed Programs	Research and development problems	May buy competitor	Environmental regulatory court case
Flat structure	Vacant Positions	Possible legislative changes	Slow markets

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. In this process, the information developed during brainstorming is organized and analyzed. The participants focus on specific topics, analyze these topics, develop solutions, and execute those solutions.

Pareto diagram: An Italian economist, Velfredo Pareto, discovered a rule while studying distribution of income in 1897. He found that 80% of the wealth of the country was controlled by only 20% of the families. 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.

Occurrence of 20/80 rule in various situations:

1. More than 80% of scrap in a manufacturing plant might be generated by less than 20% operators.
2. More than 80% of the office errors in an office might be due to less than 20% of office staff.
3. More than 80% of items in an inventory might cost less than 20% of total inventory cost.
4. More than 80% of the turnover of a company might be generated by less than 20% of the products.
5. More than 80% of the defective items might be produced on less than 20% of the machines.

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.

Step-wise procedure to construct Pareto diagram:

1. Decide on what defect data are to be collected (e.g. machine-wise defects).
2. Decide on time period to be covered for the collection of above data. This is determined by the type of problem and frequency of data generated.
3. Collect data on the defect area determined in step 1 for the time period established in step 2.
4. Design a tally sheet and mark occurrence of classified defect by the tally mark. The total of tally marks for each cause will indicate frequency for that particular defect cause.
5. Arrange the order of defects in descending order of frequency of occurrence and calculate individual percentage of occurrence of defects.
6. Draw a horizontal axis and at the each end of it draw two vertical axis. We divide the horizontal axis into a number of intervals equal to number of classified defect sources. We mark the left vertical axis with a suitable scale denoting number of defectives and the right vertical axis with a suitable scale showing cumulative percentage defectives.

Table 3. Illustrative data constituting simple Pareto diagram.

Cause of high BOD discharges	Frequency of occurrence
Exceeding treatment plant capacity	12
Malfunction of activated sludge unit	4
Introduction of concentrated wastes to treatment plant	9
Pump failure	3
Bypass for repairs	5
Power failure	2

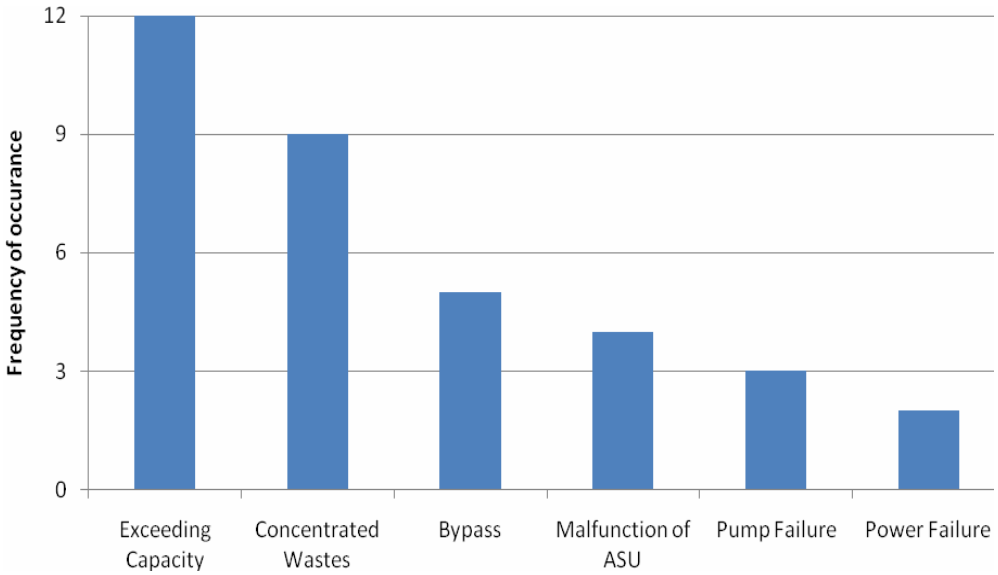


Fig. 3: Frequency of occurrences against the causes of high BOD discharges.

7. Construct the column to represent the number of defectives classified by sources.
8. Mark the cumulative percentage values by thick points and join these by straight lines.
9. Put legends and marking on various axis to enable quick comprehension of the Pareto diagram.
10. Use the Pareto diagram to help in reduction of a defect situation.

The most common cause of high BOD was exceeding the plant's capacity. The least frequent cause was power failure. Fig. 2 shows that the most common cause, exceeding plant capacity, accounted for 34% of the high BOD discharges. Concentrated wastes accounted for a total of 60% of the high BOD events. It should be noted that frequency of occurrence is not the only consideration when examining potential significance of the Pareto chart data. For example, there may be a problem or cause that does not occur very often, but each occurrence is very costly. If so, this problem or cause may require correction first.

CONCLUSION

The professional, social and legal responsibility that rest with the pharmaceutical manufacturers for the assurance of product quality are tremondous. It is only through well organised, adequately staffed accurately performed process and dosage form control before, during and after production that adequate quality assurance of the product can be achieved. It should be realised 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. Product quality must be build into and not merely tested in the product. The pharmaceutical manufacturer assumes the major responsibility for the quality of his products.

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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