# An Assessment of Total Quality Management in Parma Industries

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**Abstract**

Pharmaceutical product quality has always been a major source of worry for regulatory bodies around the world. Maintaining medication quality is critical since drugs and pharmaceutical items are provided directly to patients or customers, and poor medicine quality is not only a health threat, but also a waste of money for both the government and individuals. As a result, the pharmaceutical industry's most significant goal is to adopt an effective quality policy. Total quality management (TQM) can efficiently attain quality. TQM plays an important role in the pharmaceutical sector, from the inception of the industry through the safety of the marketed drug till it is consumed. Total quality management is a multifaceted approach that entails adhering to quality standards in all aspects of pharmaceutical manufacturing. The purpose of this review is to provide a broad overview of the TQM concept and the many management strategies that contribute to pharmaceutical quality improvement. This review paper presents a quick overview of how various techniques and practises, such as the numerous regulatory criteria that lead to the practical application of this concept include quality by design, quality risk management. This review study will assist new researchers in gaining an understanding of overall Quality Management, since it discusses QMS, cGMP, Regulatory Guidelines, TQM, and ICH Guidelines. In addition, this article provides a brief overview of current TQM industrial practises as well as the various opportunities for technical breakthroughs in real-time quality management to improve TQM outcomes.

**Keywords:** Quality management system, Total quality management (TQM), Good Manufacturing Practices (GMP), Quality by design, Quality risk management (QRM), ICH (International Conference on Harmonization).

**Introduction**

In today's world, the pharmaceutical industry is a critical component of the health-care system, as it is responsible for the development and marketing of medicinal products for the treatment of various diseases, as well as conducting research for the development of new medicinal products for the benefit of humanity. Poor medicine quality is accountable for health problems and results in massive waste of capital and wealth for both the government and the person. People are intelligent and capable of selecting items that meet their needs. When it comes to the pharmaceutical industry, quality is one of the most important aspects, and it receives a lot of attention due to the competitive environment. As a result, maintaining quality with continual improvement in facilities is critical in the pharmaceutical industry. Regulatory agencies in several countries have identified some flaws in old quality

management systems, and they are eager to adopt this Total Quality Management method (TQM). The concept of total quality control was applied in the early days, and quality was secured only based on quality control parameters. However, because it comprises complete records such as standard operating procedures for each process and step, validation records, master formula records, and batch production records, TQM entails building quality during the development and manufacturing of a pharmaceutical product.

As can be seen, the pharmaceutical industry has a lot of demand and prospects, and the Indian government and numerous Indian pharmaceutical businesses are moving into it. Though there are many options, there is also a lot of competition. As a result, in order to succeed, businesses must maintain high-quality products and services. Quality Management Systems (QMS) and Total Quality Management (TQM) are two examples of techniques that aim to enhance quality and performance to meet or exceed customer expectations. This can be accomplished by ensuring that all quality-related functions and processes are maintained throughout the organisation. These are now being acknowledged as generic management tools that may be used in both the public and private sectors. Different aspects of quality management, guidelines, the idea and techniques of TQM, and the impact of TQM on pharmaceutical companies are explored in this paper

**Discussion**

1. Quality: The term 'quality' is frequently used. Though quality appears to be a simple phrase, it is difficult to describe accurately. Quality is also referred to as "what the consumer wants." We can refer to a customer as either an internal or an external one. The term "internal customer" refers to someone who works in the process sector. An external customer is someone who, in most cases, purchases a product or service and receives it as a final result. In the pharmaceutical industry, quality has become an extremely essential concern. The globe has come together and introduced the notion of current Good Manufacturing Procedures to improve the scope of quality and harmonise quality practises all around (cGMP). Because of the efforts of many regulatory authorities around the world, there has been a growing awareness of the importance of pharmaceutical product quality. Quality is defined differently by different people based on their point of view. Quality can be defined in a variety of ways, including compliance to standards or specifications, fitness for use, and fulfilling customer requirements or expectations.

**2. Quality Management System (QMS):** A quality management system (QMS) is a system for documenting processes, procedures, and responsibilities in order to meet quality goals and objectives. A quality management system (QMS) is useful for coordinating and directing an organization's actions in order to meet customer and regulatory standards. It also aids in the constant improvement of its effectiveness and efficiency. Quality management entails overseeing numerous departments and sectors to assure a high-quality product. Quality control, quality assurance, and quality improvement are the four elements that make up quality management. ISO 9001 is a globally recognised method for developing rules, policies, processes, and procedures that ensure products and services meet specified quality standards. The ISO system ensures that products and services satisfy the needs of customers and increases customer satisfaction. This organisation has a number of countries as members, allowing it to be recognised internationally and recognised as the gold standard for QMS processes used around the world.

**3. A Brief History of Quality Management**: In the 1980s, the need for enhanced product quality became more apparent, and it was accepted that the United States was falling behind several developing countries, most notably Japan, in terms of product quality. Many tools and procedures have been used to identify quality concerns and take remedial steps to enhance product quality for decades. In the 1920s, Bell Labs statistician Walter A. Shewhart devised a series of strategies to eliminate quality flaws. In 1931, he published "Economic Control of Quality," which is today regarded a classic. In the 1940s, another statistician, Joseph M. Juran, coined the term "Pareto analysis." According to him, a relatively small number of reasons account for 80% of all quality issues. Phillip Crosby worked with International Telephone and Telegraph for his whole career, and he documented it. He emphasised that repairing something that was not done correctly the first time involves exorbitant costs. In his book "Quality is Free," he explains his thoughts. Feigenbaum created a novel concept for Total Quality Control in the 1940s. His research shows that it is critical to increase not only product quality, but also the quality of all functional domains, not simply production. These concepts were further detailed in the book "Total Quality Control." Quality Control identifies and eliminates components that do not meet the specified standard. SPC (statistical production control) is a novel concept that involves the use of statistical approaches in sampling and inspection. The quality control and inspection department focuses on detecting faulty products and preventing them from leaving the factory. Deming and Juran, two American quality gurus, started the quality improvement movement in the United States. They discussed the ideas of quality assurance and overall quality control (TQC). The first area that comes before and during the event process is where quality assurance is concerned. Total Quality Control (TQC) is defined as "a management framework for ensuring ongoing excellence." The word 'total' here denotes that the entire company is dedicated to the pursuit of purity and quality. Companywide quality control (CWQC) was another name for it.

**4. Guidelines of Pharmaceutical Quality:** The most important guidelines that are widely used in the pharma industry are:

**4.1 WHO Guidelines:** The World Health Organization (WHO) is in charge of health policy. GMP (Good Manufacturing Practices) guidelines for pharmaceutical products are provided by the WHO. The first draft document on good manufacturing practises was prepared by the WHO.

**4.2 FDA (Food and Drugs Administration) Guidelines:** To assure the quality of its goods, the safety of its employees, and the environment in which it operates, the pharmaceutical business in the United States must adhere to a number of criteria. Other countries' pharmaceutical industry must also follow USFDA requirements in order to sell their medicines in the US market. Pharmaceutical businesses have just recently begun to use the FDA's cGMP (Current Good Manufacturing Practices) method to preserve their product's intended quality. FDA changes industry rules on a regular basis, and all FDA-approved plants must follow these FDA guidelines all over the world.

**4.3 ICH Guidelines:** The ICH stands for the International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use (International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use). It is a unique non-profit project in which regulatory authorities from the United States, Japan, and Europe have joined together to standardise pharmaceutical industry procedures. The

fundamental goal of this harmonisation is to build a system for efficiently utilising available human and material resources and developing new medications while ensuring quality, safety, and efficacy to protect individual health.

**ICH Q10 Guideline:** The pharmaceutical quality system is detailed in this guideline. This is an optional policy that serves as a guide to converting GMP into business practises in the organisation. Implementing ICH Q10 throughout the product lifecycle is critical for facilitating continuous improvement and boosting the system's ability to improve product quality.

**4.3.1 Objectives of ICH:**

1. To guarantee that a medicine is available on the market as soon as possible in order to enhance public health
2. Maintaining quality, safety, and efficacy standards.
3. To lower the cost of drug registration. To make the process of developing new drugs more efficient.
4. To bring medicines to the market at a more affordable price.
5. To reduce the usage of animals while maintaining product safety and quality

**5. General Practices recently applied in Pharmaceutical Industries:**

**5.1 Quality Risk Management (Q9):**

To us, risk management is not a novel notion. In general, risk management is something we do all of the time. Quality risk management is defined as a technique for assessing risk, controlling risk, communicating risk, and reviewing risk to the drug-quality. product's It is a widely used tool in the pharmaceutical business for assessing medication risk

**5.1.1 Definitions of Risk:** The literal dictionary meaning of risk is “the possibility of loss or injury”. In simple words it is the potential undesired outcome. “By ICH Q9 guideline it has the definition as the combination of the probability of occurrence of harm (undesired effect) and the severity of that harm”.

**5.1.2 Definition of Quality Risk Management:** "It is a systematic procedure for assessing, controlling, communicating, and reviewing risks to the quality of a medication (medicinal) product throughout the product's lifecycle." The QRM is made up of several aspects, including risk identification, data analysis, risk planning, risk tracking, and risk control. These variables are depicted in the diagram below.


Figure 1: Quality Risk Management Components

5.1.3 Quality risk management includes:

**Identification of risks:** Identifying dangers before they become significant is critical. We may utilise our employees' expertise and knowledge to identify risk by incentivizing them to participate in the process. An organisation can ask everyone to identify any hazards they have ever encountered while performing a task or performing a procedure. During the process, the company can also ask the team to highlight any existing hazards or any risks that may occur in the future.

**Analysis of data:** After the team has compiled a list of all current and potential threats, the riskdata must be analysed. During this procedure, the team will estimate the risk's probability of occurrence, and then assign a risk rating depending on the risk's impact or severity. As a resultwe can prioritise the risk for mitigation based on the risk assessment. This procedure is also known as risk assessment.

**Planning:** Once the risk rating has been established and the priority for mitigating the risk has been established, the organisation must plan for the risk mitigation. In order to control risk, a number of possible practical solutions must be identified, and then a path to minimise those risks must be established.

**Track:** Once the plans for risk mitigation have been identified, we must monitor them in order to better control the risk.

**Control:** This step entails keeping a close eye on the plans that have been devised to deal withthe risks. To achieve this, strong communication with the team and stakeholders is required for improved continuing monitoring and control of potential risks. As a result, we can eliminate or lessen the hazards associated with our product.

**Communication:** After the risks have been mitigated, all of the data and conclusions from the Quality risk management process must be disseminated to all employees so that everyone is aware of the risks and the repercussions of those risks. As a result of this QRM process, organisations can deal with product risks while maintaining the high quality of their products and services.

The following diagram depicts the entire Quality Risk Management Process.

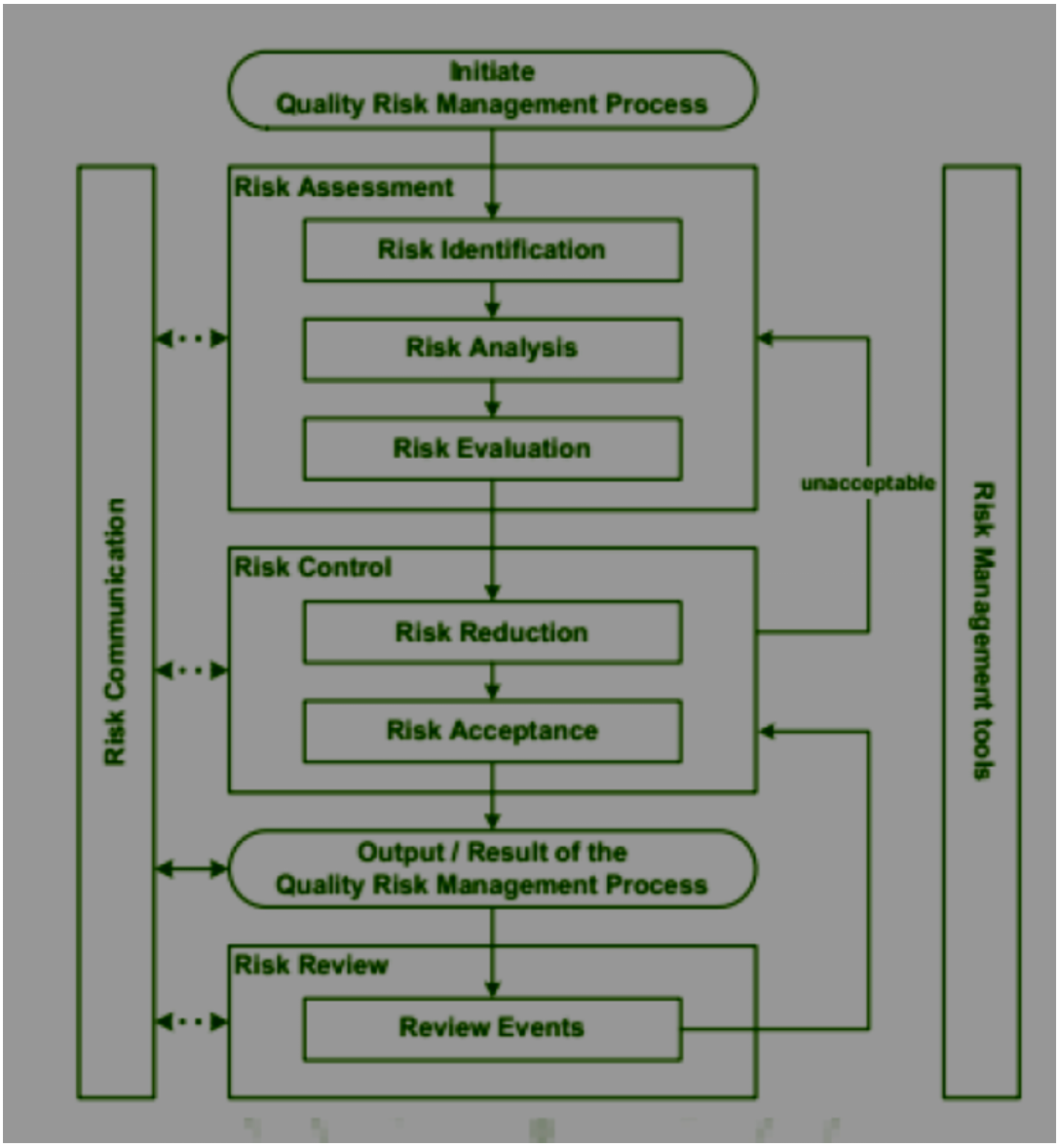


Figure 2: Typical Quality Risk Management Process

**5.1.4 Methods and Tools for Risk Management:**

1. Failure Mode Effect Analysis (FMEA)
2. Failure Mode, Effects and Criticality Analysis (FMECA)
3. Fault Tree Analysis (FTA)
4. Hazard Analysis and Critical Control Points (HACCP)
5. Hazard Operability Studies (HAZOP) 6. Preliminary Hazard Analysis (PHA)

**5.2 Quality by Design (QbD):** "Quality by design is the methodical approach to development that begins with established objectives and stresses product and process control, based on quality risk management," according to the ICH Q8 standard. Joseph M Juran was the first to explain the notion of QbD. According to him, quality may be embedded into the product itself through good planning. While formulating, we can utilise several statistical methods to optimise the composition of medication ingredients. ICH Q8 establishes design space based on the idea that quality cannot be proven into a product but must be designed into it. To use the QbD approach effectively, one needs have a solid understanding of the

product and the ongoing process. While performing the process, one must be aware of the important process parameters and critical quality features. It entails experiment design. It improves root cause analysis and change management after modifications have been approved. We can't just increase the number of tests and the frequency of testing to enhance quality. We must consider how to improve the product's quality.

**5.3 Corrective Action and Preventive Action (CAPA):** Any organisation that is experiencing nonconformities or noncompliance difficulties, including legal compliance issues, should investigate them. The investigation and treatment of system flaws or non-conformities will prevent a repeat of the same trend or pattern of deviations. Manufacturers will be able to predict future problems and prevent them by analysing trends and adopting preventive actions. Rather of addressing problems, the organisation should focus on preventing them. Preventing problems is usually easier and less expensive than correcting them later. Problems are chances to grow and improve, and businesses should begin to think in the same way.

Corrective activities are those that are conducted after an incident has occurred. These are the steps done to eradicate the problem's current causes in order to prevent it from reoccurring. Preventive actions are measures that can be made prior to an event to prevent it from occurring. These are the steps performed to eliminate non-conformity as a source of possible problems. The "Root cause analysis" technique is particularly useful for identifying the causes and taking remedial and preventive actions based on that information.

In general, CAPA and root cause analysis experts advise that root-cause investigations follow the phases outlined in the diagram.

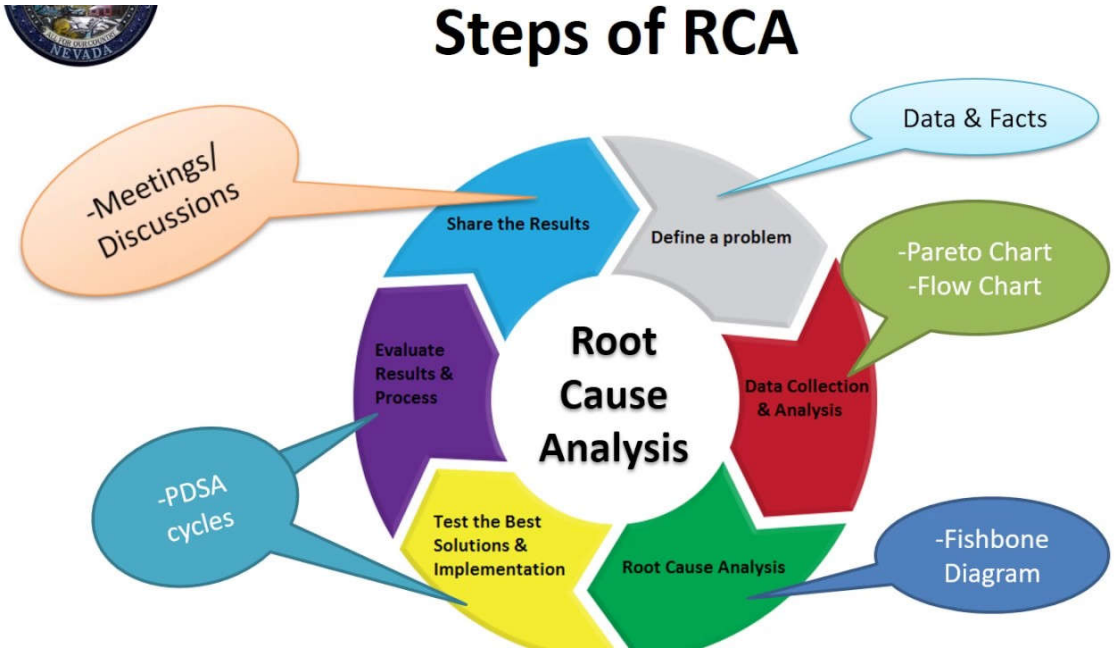


Figure 3: Basic Step of Root case Analysis

**5.4 Process Capability Analysis:** The statistical comparison of the "Voice of the Customer" (VOC) with the "Voice of the Process" (VOP) is known as process capability . VOC is largely determined by the needs of the consumer. The process specification limits, which are fixed, define it. Control limitations, which are based on performance data, define VOP. A

process capacity study can be done to examine whether or not a process is capable of meeting the requisite criteria. To conduct this comparison, potential capability (Cp) and actual capability during production (Cpk) were developed. This management tool may calculate process performance. When the process is functioning inside the predefined standards or these indices, we may state that our process is performing very well in terms of quality.

**5.5 Process Analytical Technology (PAT):** Process analytical technologies (PAT) are useful for providing fast analysis of crucial quality factors within a product, thus improving the end product's quality. PAT is used to create a system or facility that will produce high-quality goods. The primary goal of PAT is to comprehend and regulate the manufacturing process, as well as to create and implement methods that consistently achieve the needed end-of-process quality. By designing the system, PAT ensures that quality is built into the product. Organizations can eliminate batch reworks/rejects, reduce production time-cycles, boost production operating time, and improve manufacturing efficiency by implementing PAT.Many pharmaceutical companies have adopted the PAT system, and companies like GlaxoSmithKline and Sanofi-Aventis have submitted a number of successful PAT-based comparability protocols

**6. Total Quality Management (TQM)**: A Concept Total Quality Management (TQM) is an organization's integrated approach to achieving quality at every stage and at every level. TQM stands for "to fulfil the customer's quality expectations." This is the quality that is centred on the consumer. TQM is a relatively new quality control concept. TQM can alternatively be characterised as value for money, ease of use, customer happiness, and a commitment to quality. TQM is defined by the International Organization for Standards (ISO) as "a management approach for an organisation, centred 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 organisation and society." ISO 8402:1994 defines TQM as "a management approach for an organisation, centred on quality, based on the participation of all its members and aiming at long-term success through customer satisfaction and benefits to all members Although Quality Assurance employees are responsible for ensuring product quality, it is the responsibility of numerous departments and disciplines at all levels to take responsibility and ensure quality. Attaining quality at every level requires a collaborative effort from the entire team, not just the top management. This process of involving all functional departments in the entire organisation greatly aids in identifying and satisfying customer needs. Finance, marketing, service, procurement, and the quality warehouse, i.e., finance, marketing, service, procurement, and quality warehouse, i.e., finance, marketing, service, procurement, and quality warehouse, i.e., finance, marketing, service, Only then will it be feasible to ensure total quality by working hand in hand with the manufacturing department. Finally, as a result of enhancing total quality, the company's performance will improve as well. The physical plant design, space, proper ventilation, cleanliness and proper routine sanitation during product processing, strict implementation of standard operating procedures (SOPs), effective management of deviations and incidents, active participation of each and every team member in identifying risks and root causes, effective CAPA management, and Change control management, viz.

As a result, total quality management (TQM) entails the following:

1. Customers must be satisfied the first time, every time;

2. Providing employees with the tools they need to solve problems and reduce waste;
3. More than a managerial method, a working style, a culture;

**6.1 The key elements of the TQM approach are:**

1. Focus on the customer: The organization's most important responsibility is to identify its customers (internal and external). Customers of the drug product may be external customers, while workers of the company may be internal customers. Organizations should think about and focus on each and every customer's expectations, with customer happiness as the primary goal..
2. Employee Involvement Because quality is the responsibility of every employee, the organisation must utilise each employee's experience and knowledge in the process of quality improvement. The organisation must involve all employees and urge them to participate actively in this movement so that they may contribute to the improvement of quality.
3. Continual improvement: Improving quality and maintaining it is a never-ending process in which each person consistently contributes to the improvement of company performance, process yield, and product or service attributes. The goal of continuous improvement is to increase quality at regular intervals and sustain it. This will, in turn, serve to improve the overall quality of the product or service, as well as the overall performance of the business.

**6.2 Management Tools For Process Analysis, Planning And Decision Making:**

As we all know, the only method to improve the quality culture and set the quality benchmarks for businesses is to maintain comprehensive quality. We must efficiently manage, analyse, and plan processes in order to meet customer satisfaction and achieve the target quality in every element of the product's lifecycle. Each process, policy, activity, product, and service must specify and fulfil the environmental aspects and impacts. We must identify the objectives for each process, as well as give the detailed information and analysis of all processes. Flowcharts, cause-and-effect diagrams, brainstorming, histograms, SWOT (strength-weakness-opportunity-threat) analysis, Pareto diagrams, and other quality management tools can help achieve this goal.

**6.2.1 Cause-and-effect diagram (Fishbone Diagram):** The CE diagram (also known as the Fish-Bone Diagram) is the result of a brainstorming session in which various causes for an effect are identified. The diagram that results depicts the relationship between the identified causes and effects that are being investigated. For example, in any manufacturing process, the various factors that can affect it can be grouped into the so-called 4 M's, i.e. manufacturing process, material, manufacturing process, manufacturing process, manufacturing process, manufacturing process, manufacturing process, manufacturing process, manufacturing process, manufacturing process, manufacturing process, manufacturing process Materials, men, machines, and processes are all important. As a result, variations in materials, machines, staff, and processes can lead to significant differences in ultimate product quality. As a result, any TQM effort that employs this method to investigate problems in a manufacturing process will typically begin with these major causes.

**6.2.2 Brainstorming:** Putting the proper group together and letting them brainstorm may have a huge impact, and this strategy has a lot of potential in a continuous improvement

programme. Many quality programmes use “quality circles” or “focus groups” to develop ideas for programme development and improvement. These are comparable to brainstorming followed by data analysis in idea. Brainstorming can be employed for specific problems or as part of the day-today activities. People who are affected by the problem should participate.

**6.2.3 FADE:** The FADE (Focus, Analyze, Develop, and Execute) process, popularised by the total quality management (TQM) movement, is another technique that can be used to build on the ideas generated during brainstorming. The information gathered during brainstorming is organised and analysed during this step. The participants concentrate on a few subjects, study them, come up with answers, and then put those suggestions into action.

**6.2.4 Pareto diagram:** An Italian economist, Velfredo Pareto, found a rule while examining distribution of income in 1897. He discovered that just 20% of the country's wealth was held by only 20% of the families. The guideline was later applied to corporations by management experts. Juran noticed that the vast majority of quality issues are caused by a limited number of defect types resulting from a small number of sources. As a result, if these critical few reasons are investigated and controlled, quality issues can be resolved to a large extent. In organisational problem analysis, it has been discovered that 20% of all causes account for 80% of all problems. As a result, by resolving 20% of all causes, approximately 80% of the problems can be resolved. The 80/20 rule, sometimes known as the 'vital few' and 'trivial many' principle, is based on this notion

Step-wise approach to generate Pareto diagram:

1. Decide on what defect data are to be collected (e.g. machine-wise defects).
2. Decide on a time frame for collecting the data mentioned above. The type of problem and the frequency with which data is created define this.
3. Collect data for the time period established in step 2 on the defect area determined in step 1
4. Create a tally sheet and use the tally mark to record the incidence of each categorised defect. The total number of tally marks for each defect cause will reflect the defect's frequency.
5. Arrange the flaws in ascending order of frequency of occurrence and calculate the total Individual defect occurrence percentage.
6. Draw a horizontal axis with two vertical axes on either end. The horizontal axis is divided into a number of intervals equal to the number of defect sources classified. We use an appropriate scale to indicate the number of defectives on the left vertical axis and a suitable scale to represent the cumulative percentage of defectives on the right vertical axis.
7. Create a column to indicate the total number of defectives sorted by source
8. The cumulative percentage values are represented by thick points, which are connected by straight lines
9. Put labels and markings on various axes to make the Pareto chart easier to understand the diagram.
10. To assist in the reduction of a defect scenario, use the Pareto diagram

**6.3 TQM has the following benefits:**

1. Improves reputation by locating and resolving flaws and issues.

2. Employee morale is improved as a result of added responsibilities, teamwork, and involvement in TQM decisions.
3. Reduced waste means fewer defective items and no need for a separate quality control inspector, lowering costs.

**6.4 TQM has the following disadvantages:**

1. The cost of the initial introduction.
2. Benefits may take several years to manifest.
3. Change may be resisted by employees

**6.5 Causes of Failures in Implementation of TQM Approach**: Total quality management is a proven strategy that has resulted in significant financial benefits for many pharmaceutical companies. However, quality efforts in some other companies have failed and yielded marginal results. According to studies, just one-third of companies got major outcomes, onethird were disappointed, and one-third got moderate results. According to Brown, Hitchcock, and Willard, the following are causes that may arise throughout the implementation process:

1. Putting all of one's attention on short-term financial success at the expense of system improvement
2. To manage the underlying processes, Quality Improvement necessitates a shift in thinking
3. Managers interfering with teamwork.
4. Procedures and processes that are sloppy
5. TQM approach is not well understood.
6. The organisational structure has many layers.
7. insufficient training and education

**7. Conclusion**

TQM is the most effective method for pharmaceutical quality control. Many regulatory bodies strongly advise it, but it is still not fully applied in all businesses, particularly in India. Because India is one of the world's top exporters of pharmaceutical items, thorough TQM adoption is critical in the Indian setting. Despite significant progress in product development for real-time online production and packaging monitoring, the majority of industries' low use of these technologies remains a key source of worry. This essay is a call to worldwide regulatory bodies and pharmaceutical businesses for stronger enforcement and true implementation of TQM methods in industry in order to produce high-quality medicines.

The manufacturer needs to be able to,

1) manage the causes of variance in product quality, such as materials, machinery, and processes as well as men
2) Ensure that the best manufacturing and packaging methods are used.
3) ensure that the findings of the testing are in accordance with the standards or specifications
4) Through a well-organized complete quality assurance system, ensure product stability and undertake other operations linked to product quality.

Certain basic operating principles should be created and should always prevail for the overall quality management system to function properly. First and first, control decisions must be

made purely on the basis of product quality considerations. Second, the operation must strictly comply to the established standards or specifications as determined by systemic inspection, sampling, and testing, and it must continually try to improve the current standards or specifications' levels. Third, staff should have access to the facilities, funds, and environment they need to efficiently carry out their obligations. Last but not least, administratively, control choices must be independent, and they must not succumb to or be overridden by production or marketing under any circumstances. Because the control decision may affect the consumer's health as well as the pharmaceutical manufacturer's reputation, the environment required for making informed judgments is critical. Only the highest level of management should evaluate the control decision in the event of substantial differences.

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