



TOTAL QUALITY MANAGEMENT IN PHARMACEUTICAL INDUSTRY – A REVIEW

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Abstract

Total Quality Management is a statistical managerial method that is used by the pharmaceutical industry. It helps to improve the quality of the medicine. This is a practice of the client's satisfaction it plays and significant role in the medical sector. This is a regulatory body and is regulated by The Central Drugs Standard Control Organization. In the manufacturing process, any mistake can lead to unnecessary consequences. All the stakeholders and employees are engaged in the product quality process for the implementation of Total Quality Management in the pharmaceutical industry. In the pharmaceutical industry, Total Quality Management always welcomes “cost saving, accelerate innovation, facilitate entry to the global market, and increase in profit, faster time to market”. Total Quality Management's beginnings reflect on the basic concept. According to the first-word amount, all workers of the firm are intended to boost operations. This Total Quality Management should be a concentrated effort of the work. To consistently improve product quality, “company leaders should create targets that are clearly stated, offer training, money, and if necessary, hire the necessary staff”. It helps to understand and identify the problems and risks of the medicine and it tries to solve the problems and risks of the medicine. It helps to the improvement of the total decision-making process. Therefore, it helps to schedule the time management process that helps to save time and cost.

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Introduction

Total Quality Management (TQM) is a system that uses to satisfy all the customers. It very helps full for the person, therefore, it helps man. TQM leads to the development of the pharmaceutical industry. These developments help the person and the product. The involvement of the employees and management helps to increase the development of the pharmaceutical process.

There are many major elements are, “quality improvement in culture, Effective Control continuous improvement in processes, and focus on customer requirements”. Moreover, there are a huge number of key elements that play an important role, TQM integrity, trust, training, teamwork, leadership, recognition, and communication. The pharmaceutical industry helps to manufacture, sell, and develops. The illness of the person is reduced as per need. And this also helps to produce the medicine and drug. Moreover, this TQM process helps the development of the focus of the customers and it also gathers the chance for partnership between the company and the customers. In this discussion, there is the prominent topic is TQM and the organization size of TQM, the principal of

TQM, benefits of TQM.

Organization Size of TQM

TQM has a direct and positive influence on industry and employee growth. Companies can establish and uphold natural values that pressure greater success for both clients. TQM's focus on quality helps in detecting employees' skills shortages and providing the necessary “training, education, or mentoring to address that growth”. The TQM process also focuses on the teamwork of the company. It provides more benefits to the industry [1]. It leads to the creation of cross-functional knowledge sharing and teams. It increases communication and coordination in developing personnel. The organization has many steps, including clarifying vision, mission, and values, developing measures and metrics to track CSG data, it also identifying key customer groups, surveying each customer group, and developing an improvement plan. Moreover, this process also helps to identify the critical success factors that are necessary for the business and the development of the business. Therefore, it plays an important role in the development of the organization [2]. The stepwise TQM transformation process is represented in Fig. 1.

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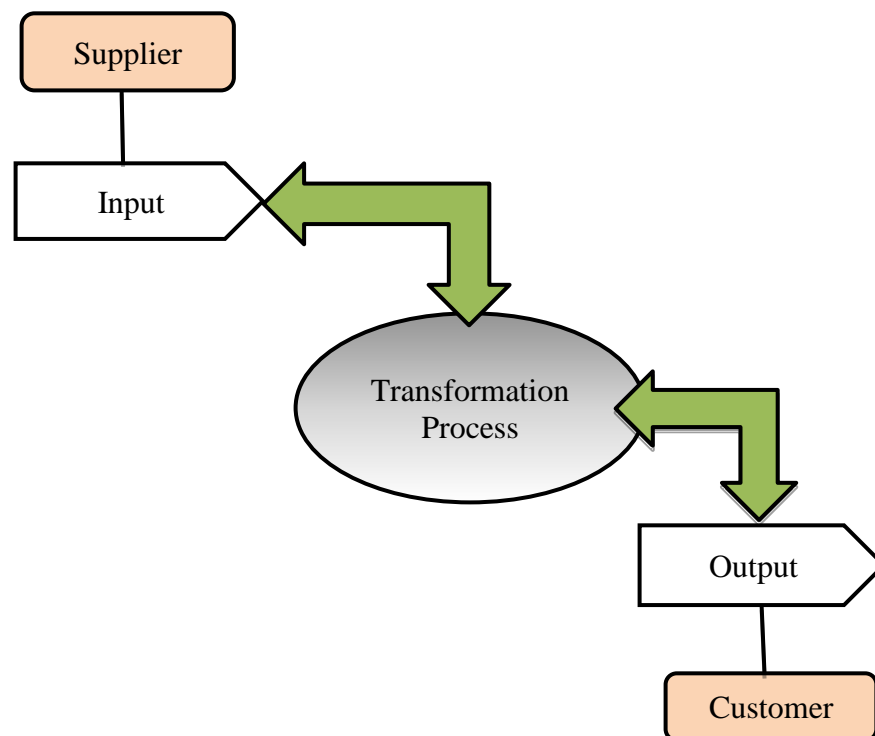


Fig. 1: A TQM Transformation process



In the pharmaceutical industry, there are the most popular types of medical products. All medical products are driven by the medical process. The main importance of this research there are various processes, structures, and interactions of the customers that improve the health systems. Because of this, there are mainly needy products qualitative medicines, effective and safe medicines. And this medicine also needs low cost, therefore customers can buy this easily. For this, the company grows as per the requirements [3].

TQM ensures the development of the products, services, and organization. Therefore, many components help the growth of the company, quality planning, quality assurance, quality control, and quality improvement. With the satisfaction of the customers, it gains its development, therefore, customers can highly like the product and services of the company. And the company is growing day by day as per the requirements.

TQM is beneficial effects that help the development of the company; therefore, employees and customers are more satisfied and that provides a big cultural value for the company. Therefore, customers are always involved in the company [4].

Benefits of TQM

TQM is a quality policy that is very helpful in the process of the development of the pharmaceutical process. There are many benefits of TQM that are very helpful in the pharmaceutical process. It is beneficial effects on the employees and the products of the company. Therefore, this TQM helps the organizational development. Employs of the organization always try to focus on the establishment of the company and uphold the cultural values that build long-term success for the customers and the employees and also the organization [5]. Therefore there are many methods that are helps to development of this pharmaceutical process.

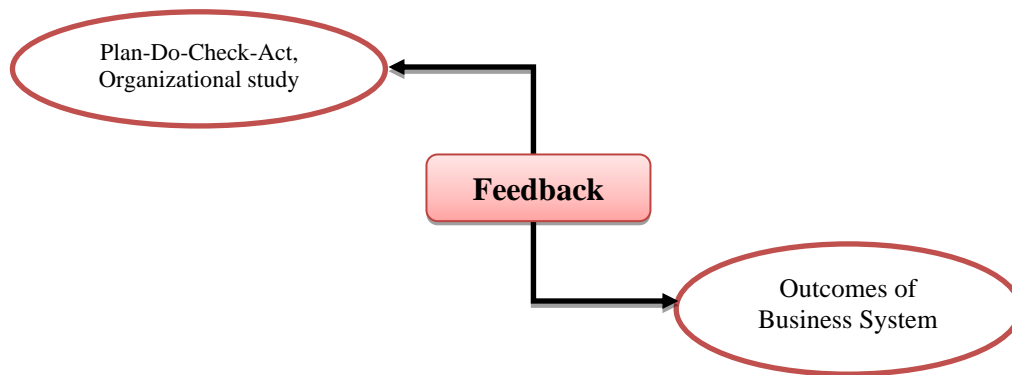


Fig. 2: Benefits of TQM

This TQM helps to development of the company by providing more satisfaction to the customers. The main benefit of this TQM process is represented in Fig. 2. This always tries to reduce the cost of the products and also tries to increase the services of the company and tries to increase the quality of the product. Therefore, customers like to choose the products of the company [6]. But it not only helps to reduce the cost and not only saves time, but it also helps to improve risk management. Moreover, this also gathers efficiency, a better understanding of customers' need, regulation of successful working practices, and improve the participation of employees. All

these are advantages of the quality management process.

- Fewer products defects

It is one of the principles of the TQM is the creation of products and services. It helps people in the process of pharmaceuticals. Therefore, people can grow themselves and grow the health of the people of the company. It reducer the product recalls, products ship with fewer defects, and future customer support of product fixes and overhead.



□ Satisfied customers

In the TQM process there is the main benefit is a higher level of satisfaction. Higher customer satisfaction is the result of elevated items in the pharmaceutical process. And this higher level of satisfaction meets consumers' needs. Increased market, revenue growth via promotions, and consumption of word-of-mouth marketing all can result in high client satisfaction [7]. And this satisfaction helps to development of the company and the industry. Therefore, the people's health also grows as per the requirements.

□ Lower costs

It is another process that helps to development of the company. If any company or industry reduces the cost price and increases the product quality that is more beneficial for this business procedure. Firms also help to save cash on customer support, product replacement, field service, and the creation of product fixes. Therefore, the result of this is limited product faults. A higher level of satisfaction among the customers grows the profit margin produced by the process of cost reductions.

□ Well-defined cultural values

TQM is a policy and the practice of the developments. It is the nature of the core values. And this also provides the TQM mindset provides also most benefits. That is a continuous process it helps to internal process. To the product development these well-defined cultural values are the main key point of the benefits of the TQM of the pharmaceutical process [8].

PRINCIPLES OF TQM

Management of total quality is an approach focusing on management for the quality improvement and the functions of a focused group of departments and providing quality services that exceed the expectations of consumers. TQM always focuses on the customer's requirements and the needs of the customers. Moreover, it also focuses on the client's development and improvement. Therefore it uses the data, strategy, and effective communication that are necessary for the development of quality management. There are many elements of TQM.

The main objectives of the TQM are “increase

employee's productivity, make sure employees are trained in quality, focus on continual methods improvement of procedures, and improve customer service”. It is a structure of the improvement that helps to improve the quality of the industry and the people's careers. The Principles of TQM was figured out in Fig. 3.

The elements of TQM are trust, leadership, ethics, training, integrity, teamwork, communication, and recognition. The main principles of TQM are discussed below:

Adopt the new philosophy for the betterment of the management process

□ Every company has to be focused on the consumer needs rather than competitive pressure and manage the services and products that meet those processes.

□ Establish a vision of quality and always try to improve the condition for the betterment of the future.

□ Management always has to prepare for the major changes in the organization for the better enhancement of the company.

□ The organization has to embrace the quality of the management for the betterment of the company.

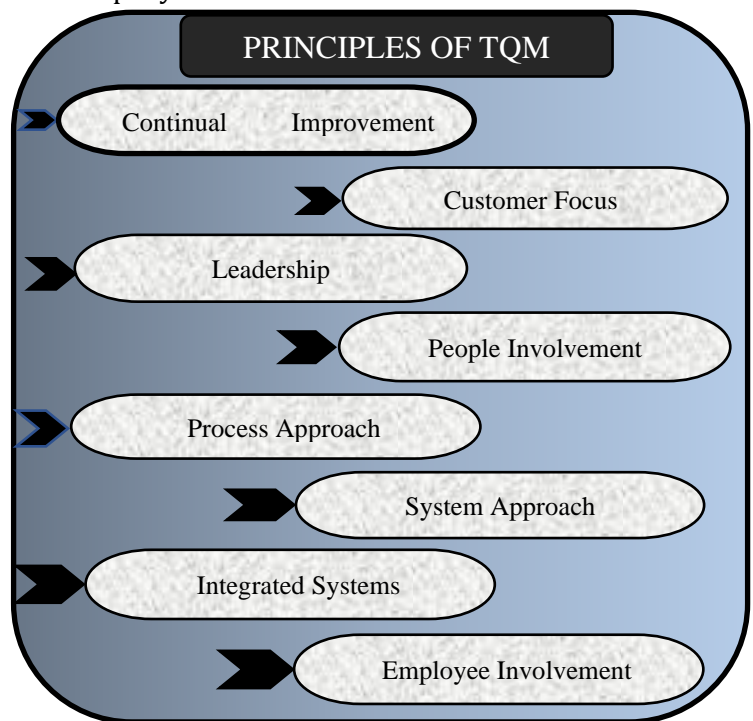


Fig. 3: Principles of TQM



Customer Focus

It is the most important quality management principle. That always focus on the peoples who buy the organization or the pharmaceutical products or services. Customers always determine the company's quality of the products. There are many products are satisfied the customers because quality products always focus on reducing the money and increasing the quality of the products [9]. Customers' focus is the most important thing that is necessary for all the work. It is s strategy that is the main strategy of business decision-making. It is a long-term strategy that is necessary for the develop loyalty and trust.

The main implementation of this TQM principle is,

- Understand and research the customer's expectations and needs. Understanding is one of the things that helps to know about the employees and the customers.
- Customers need to align with the organization.
- Measure the customer's satisfaction with communication with the customers. And other methods are using the result to find the improvement process of the company.
- Manage the relationship between the customers and the organization. A strong and effective relationship between the customers and the workers helps to grow the company as per the requirements.
- Find the balance for satisfying owners, employees, suppliers, investors, and customers.
- Increase the possibility of the satisfaction of the customers and will tell others about services and products.
- Building strong customer loyalty and this customer loyalty is necessary to grow the business.

Integrated systems

A business typically includes a considerable number of distinct departments, each with its distinct tasks and objectives. The lateral procedure that should be enhanced and emphasized in TQM is connecting various departments. But occasionally, these subdivisions

and activities work in separate sections [10]. Everyone from every department should completely comprehend the policies, standards, goals, and practices in an integrated system. Connected systems assist the business is looking for continual improvement to compete successfully. The integrated system is another process or method that is necessary for the infrastructure, enabling all costs to work as a whole. There are many methods of the integrated system those are, "point-to-point integration, vertical integration, star integration, horizontal integration".

In integrated systems, there are many implements that are necessary for the development of the company. It helps the company to grow its revenues and productivity of the company and it also helps customer satisfaction [11]. Therefore, it plays an important role in the process of TQM in The Pharmaceutical Industry.

- A work culture always tries to focus on the quality of the product.
- Use visual aids and flowcharts that help employees' satisfaction and understanding.
- Use process analysis that helps the improvement of the company.
- Making training available for the employees that also helpful for the development of the pharmaceutical industry.

Strategic and systematic approach

This principle of TQM in the pharmaceutical is formulated as having by the Organization For standardization (ISO). In the business process, this is very effective and the efficiency of an organization helps to achieve its goals and objectives. This also helps to boost by identifying, understanding, and managing interrelated activities as a system. In an attempt to enhance and expand efficiency, many processes within a research or production are controlled as just a process in the system. This strategic process helps to development of the company. Moreover, it is very beneficial for the business. Basically, all processes are very strategic in a systematic way. Therefore the business of the pharmaceutical industry grows as per the requirements. It is a strategic site that is effective, logical, and



objective and it has a part of the details.

Continual improvement

TQM always focuses on the organization's improvement. This process provides effective results for the business. This always provides high-quality products and services. That is a necessary thing for the business. The main goals and aims of the company are improvements of the organization, especially the improvement of the product quality. In productivity, quality cannot be improved without effective losses. A business or firm must always look for ways to simplify processes and operations and change its goods and services in adapting to shifting customer demands. If this continual improvement wants to maintain optimum productivity, revenues, profitability, and total customer satisfaction. The other Following guidelines should help the business. Therefore, this business is going to keep an eye on continued development [12]. This continual improvement helps to achieve quality fanfiction and the key process of improvement. Many components of TQM help in the improvement process.

Leadership

To achieve the dependent goals and aims of the company, unity among employees must be fostered through leadership. Leadership is a process that provides proper guidance to the employees and co-workers. Therefore, employees are mostly satisfied and worked very well. Employees are motivated, encouraged, and guided by the leaders. Despite the fact that there are primarily three styles of leadership in the sector. The democratic establishment is the most effective in this process. Managers can develop an environment that enables everyone to participate to achieve the organization's objectives within the business. Therefore, this process of leadership appears that leadership is an essential principle of TQM in the pharmaceutical industry.

Total employee involvement

It is a methodology that bare necessary in the pharmaceutical industry. It set the management principles that are motivated the team members, employees in particle, and individual of employees. Therefore, employees are motivated and try to problem solve, the planning process.

Involvement of people

Every turnover of workers dedicates the customers fully to the growth of the company. The industry is capable of creating products and enhancing sales growth of the company to the whole employee engagement. Therefore, the organization's entire workforce and the market of the company must be trained properly, motivated, and dedicated to meeting an interdependent goal. That is necessary to grow the organization and the sector also must establish a responsive environment where every other employee or worker will be inspired to carry out all the duties perfectly. While Consumers of the organization may be delighted as a result of the employee's engagement, motivation, and retention. This process, promotes coordination that can emerge from people getting involved.

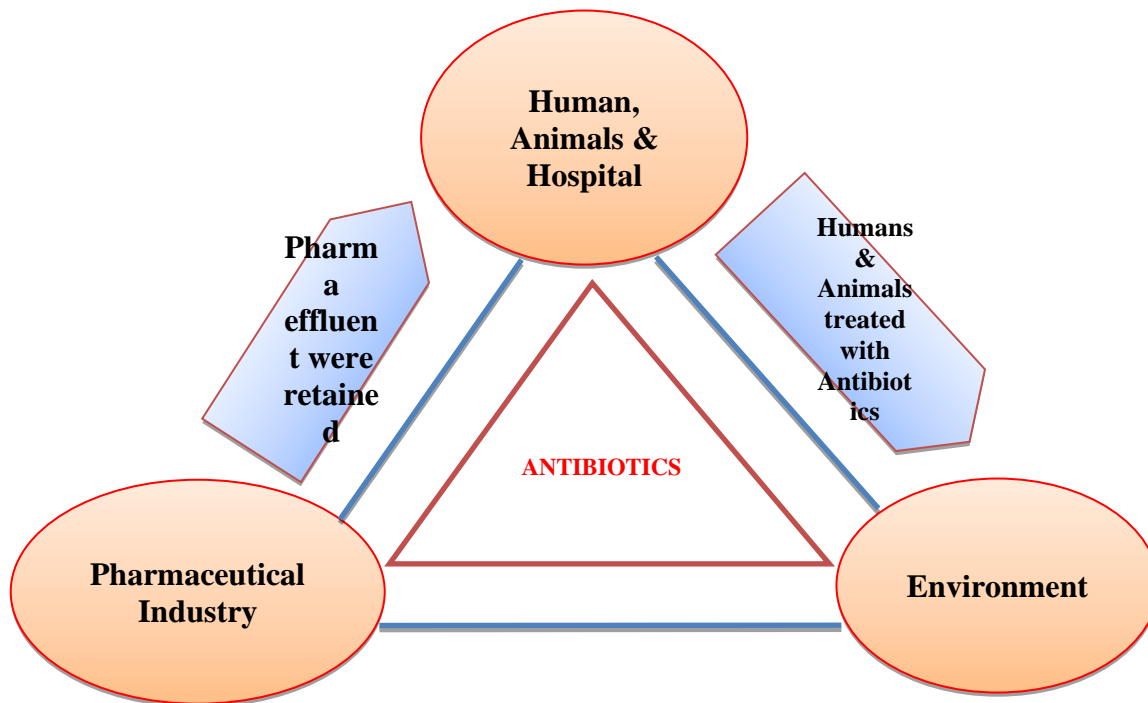
TQM and environment in the pharmaceutical industry

This process is sustainable in the pharmaceutical process this helps to achieve long-term organization. It helps to achieve success by encouraging the employees. TQM in pharmaceutical companies uses innovative techniques with no potential consequences to produce high-quality medications and high responsiveness to customers. The TQM has many key factors that are "customers focus, employee improvement, centered on process, strategic & systematic approach, communication, continuous improvement, decision making based on facts, and centered on process. This TQM in the pharmaceutical industry process includes green innovation practices, and the pharmaceutical industries code of conduct places a great focus on saving the environment [13]. The interrelation between the pharmaceutical industry, environment, humans and animals was represented in Fig. 4. Green manufacturing methods are the main key component of the TQM concept. For sustainable development, organizational effectiveness, and ecological balance, green innovation activities including climate planning, managing carbon dioxide emissions, energy-efficient approaches, water management, and wastewater treatment are necessary and crucial, all play an important role



in the industry [14]. TQM provides quality assurance to the clients that are necessary for the managing process of the customers and it also

helps to make needed corrections and solve the problems and the quality.



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Fig. 4: The interrelation between the pharmaceutical industry, environment, humans and animals

Environmental sustainability and continuous environmental progress inside the pharmaceutical industry are a result of fighting climate change processes using renewable energy. It helps the economic development, quality management, and cultural management of the company. Green manufacturing is a process that provides more opportunities for the pharmaceutical industry. This helps remove the air, water, and soil pollution and it also helps to provide a good health and well-being community [15]. Therefore, this quality management and environment in the pharmaceutical industry. To the low carbon economy, the pharmaceutical companies are dedicated to contributing to the transition. There are many risks are finds those are economic risks, physical risks, and transitional risks. In the green innovation process, TQM is one of the most important principles and philosophy is implied. In this process, there are many steps to TQM process are commitment and understanding, effective control, quality improvement culture, focus on

the customer requirements, and continuous improvement in the process [16].

There are many any factors that are helps to affect the pharmaceutical industry those are, “regulatory frameworks, growing healthcare spend, aging population, pricing pressure, health trend, growing Biotechnology industry, Direct advertising, and growing obesity rates. All play an effective role in the pharmaceutical industry. It reduces health problems and the try to solve health problems [17]. The improper disposal and drug manufacture of medicine in the pharmaceutical industry in lakes, soils, rivers, and drinking water.

- Plan for the TQM and the environment
- The main strategic planning for TQM is,
- Define the difficulty of the work.
- Locate the difficulty area.
- Schedule the time plan.
- For solve the problems or the difficulties of the work the main plan is to set targets and goals.



- Identify the best methods for solving the difficulty.
- Do for the TQM and the environment
- In the development of personnel involvement, commitments are one of the best parts.
- Perfect taring for the proper improvement of the plan.
- Improvement methods and activity.
- Checks for the TQM and the environment
- The outcome and the methodology are always compared with the TQM plans.
- If identified the gap, this is existing.
- Acts for the TQM and the environment
- Engaged in either non-conformance analysis or standardization.

Six sigma of TQM

Six Sigma is the most important thing that is used to define statistical stuff, and it may mean things to different people. Some persons will define Six Sigma as a strategy aimed to promote mostly excellent manufacturing processes. Six Sigma aims for a standard performance with only three and a half defects for every million activities, and that is in harmony with the massive body of articles on the subject [18]. Moreover, some people define Six Sigma as a transformation in corporate structure that enhances a company's standing and promotes becoming even more competitive, innovative, and productive. Although not a quantitative system, Six Sigma frequently uses use of numbers in its consumption and analysis of findings.

Some of the most successful firms in the world have adopted Six Sigma and the result of this, this is very useful for the savings of millions and millions of dollars, it plays a significant role in the speed and performance of the operations, and the emergence of new, better relationships with customers [19]. A customizable framework called Six Sigma is implemented to accomplish, protect, and enhance the success of the company. There may be a wealth of available research on the increased adoption of Six Sigma.

Six Sigma is most popular in the pharmaceutical industry, it is less effective for companies with 100 or fewer employees. And although small

organizations can use some parts of the methodology, this is not as applicable [20]. There are also advisories regarding a booming sector that provides Six Sigma certifications. Moreover, make sure any service provider offering Six Sigma services is highly authorized to do so by performing these six sigma.

Six Sigma Principle

Any Six Sigma project's purpose is to determine and resolve any problems that are contributing to the output level by establishing a sequence of moves focused around a given objective [21]. The principles of six sigma are,

- Smaller is better

It is higher than the acceptable restriction and including such setting a goal of zero for problems or failed components.

- Nominal is best

It depends on the customer service person that must speak to a client for something like a sufficient amount of time to solve a situation, but not quite so long as to inhibit productivity.

SIX SIGMA METHODOLOGIES

Six sigma always focuses on removing the variations and the increase the process of control and maintenance. It promotes standardization and flow. Six sigma laws follow two methods, which are, Six Sigma DMAIC and six sigma DMADV. Each method a different set of suggested strategies for transformational change which should be used. A data-driven technology named DMAIC has been used for positive activities goods or services such that customers are more pleased.

- Six Sigma DMAIC

There have five phases, all of which play an important role in the TQM in the pharmaceutical industry. This model helps to improve the quality of the results that are necessary for all the work [22]. Because it helps to grow the industry and expand the company in the global market.

- Define the issues or the problem of the research, the client, the specifications of the project, and the client's final performance targets.

- Analyze the method used to determine the possible factors of changes and defects to spot problems in the existing strategy that would



get in the approach of the target.

- One may evaluate the effectiveness of the existing process by establishing a data collection plan to identify defects and collect measurements.
- Control is the technique that is used to keep it on course and prevent it from developing bad habits.
- Improvement is one of the best procedures that can be done by reducing the fundamental causes of problems.

- **Six Sigma DMADV**

It is a method of continuous improvement that always tries to focus on waste and the reduction of the variables that always come from manufacturing. It is a lean six sigma methodology and the main aim of this is to reduce non-value activities. Moreover, this creates value for the customers. In the order to achieve the customer's needs, any organization builds a new process. There are many methods of DMADV that are, "analyze, define, measure, design, and verify" all of these plays a very effective role in the TQM in the pharmaceutical industry.

- The six sigma always defines the research deliverables and goals during the phase of definition. It helps to define the client's needs and requirements.
- In the phase of measurements of the six sigma DMADV is always focused on the client's need, therefore, it focuses on the project's factors. This is the most important thing to its goals.
- The next process of six sigma is the analysis, this is the finding options that are necessary for all the industry. This finding method helps to meet the client's requirements.
- After these six sigmas of the DMADV is focused on designing. It is a business model that is used to help meet the client's requirements.
- Verifying is the last and final method so the six sigma of the DMADV it is verifying the new medals that meet the client's requirements.

Six sigma implements roles

Executive Leadership

The CEO Representatives of executive management who are responsible for formulating

the strategy for the Six Sigma application fall in this category. Moreover, leaders will provide the tools that are essential to building revolutionary theories into practice.

Master black belts

These employees work completely with the Six Sigma methodology, they are mentoring Black or Green Belts or supporting Masters. They are chosen by Leaders and given the responsibility of maintaining the Six Sigma methodology consistency.

Black belt

Black belts are fully professional things that are played like the main responsibility of the team leaders. While the champions, executives, and master black belts always focus on the 3 six sigma projects. There have many methods that are helps to understand. These are, DMAIC and DMADV [23]. Both are statistical methods it helps to estimate the amount of responsibility. And helps to identify the risks and the problems and also try to reduce the problems and the risks.

Green belt

It is part-time professional things there are many varieties of duties. These duties are including with the black belt project and the leading smaller projects. Therefore it tries to solve the problems and reduce the problems. This is necessary for TQM in the pharmaceutical industry. Duties are included the data, analyzing the information, and executing experiments. Therefore it provides the best strategy for the industry.

Benefits of six sigma

Six sigma plays an important role and Six sigma has many benefits, the main benefits of the six sigma are eradication of waste and variation from the process and the methods of the industry [24]. And the six sigma helps to identify the problems and helps to solve the risk in the problems of the work. Moreover, this also helps the improvement of the methods and the process.

- It helps to decrease waste, that's why one can reduce the amount of waste. It is a strategical methodology that is always focused on decreased waste. These are the main benefits of six sigma therefore, it helps to save money, resources, and time,



- One can increase efficiency. It is an effective process that helps to reduce waste.
- One will decrease the risk to the industry. Reduction of the risk is a very effective benefit of six sigma because it helps to grow the industry and gain knowledge.
- One can grow money and increase productivity and profitability.

Origin of six sigma

Six sigma is strategic methods and techniques that are helps to improve and the development of the manufacturing quality. It is introduced by Bill Smith who is an American engineer at Motorola in 1986. Identifying and reducing the problems and the difficulty reduces the variability in the business process.

The term six sigma comes from the manufacturing process of the statistical methods.

CONCLUSION

A service called TQM is used to satisfy each and every consumer. Quality management always tries to improve their products for the satisfaction of consumers. To achieve the goal of customer satisfaction producers, increase the quality of products day by day. It greatly benefits the individual, the group benefited the company, and hence benefits mankind. The growth of the drug companies is a result of TQM because of the quality management section of business development. These advancements benefit both the individual and the product because the increase in innovation in products creates new achievements for the consumers this is a benefit for producers. The management's and employees' younger and older people to the pharmaceutical processes continued improvement. "Quality management improvement in culture, Effective Control continual improvement in processes, and emphasis on customer requirements" are just a few of the key components. These co-components of different quality management develop different types of management. A significant number of other crucial factors also come into play, including quality improvement integrity, trust, training, participation, organization, recognition, and communication. The pharmaceutical industry helps in production,

supply, and sales, these things develop or uplifted the pharmaceutical industry. As a conventional system the quality of the product mainly depends on the final product of the producer. TQM approached is a combination of efforts designed by any organization puts an impact among the organizations. With the improving technology every company tries to improve their quality of the product if the company successful to done this opportunity it will be a great opportunity for the organization. The TQM is a recommendation of TQM process which develops the quality of management. Quality of a product is an extensive advancement for the organization worked for the development of the company. To be digital is the great opportunity among the companies so the organization always want to do that.

CONFLICT OF INTEREST

Authors declare no conflict of interest.

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