

Quality Management System: A Much-Needed Tool to Ensure Total Quality Management

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ABSTRACT

The demand for quality products in the market has increased drastically in the past several decades. Thus, to survive in the competitive world it has become very important for every organization to have a well-structured and planned management system. The system encompasses all aspects, it not only works outside the organization but also strengthens the core and delivers a top-quality product to the end-user. In order to deliver the top-notch product total quality management has merged out of the quality management system and has enhanced the efficiency of the organization to produce a quality product to many folds. Quality management system along with the total quality management leads the organization to reach the zenith of zero percent defect and hundred percent customer satisfaction. This review article helps you to understand the intertwined concept of the quality management system and total quality system within the organization. They both share the same vision of customer satisfaction by producing the top quality product yet work on different levels to achieve it by using different techniques.

KEYWORDS: Quality Management System, Total Quality System, PADA cycle, Quality control, Quality culture

INTRODUCTION

Every organization is striving hard to outrace one another in this competitive era, where the main goal to produce a top-quality product and maintain that brilliancy for years. Maintaining the quality with an effective quality management system not only beneficial for the end-users but also is a boon for the organization itself. The quality management system is not only a procedure but a complete system in itself where innovations are welcomed and undertaken by the firms to give their products a zero-defect status. Without proper management the firm collapses, thus the firm must have a body that keeps an eye on the work and cross-check every process at every step. Here the role of the quality management system and total quality management comes, together they decrease the chance of any breach within the quality of the product manufactured from a particular organization. A thin line runs between Quality Management System and Total Quality Management, although they work in the same direction yet they have different ways of achieving the same goal.

The Quality Management System

It is a structured collection of policies, business processes, documented procedures, records, and responsibilities associated with every department of the organization. Altogether, to ensure reaching the ultimate goal of customer satisfaction. The QMS anchors a firm or an organization to work together towards producing and maintaining the quality expectations of customers under the regulatory

standards. It aims to cater to the needs of the consumer or the client not just by producing the requisite amount of the material but also tries to show the brilliance and the capability of the firm to produce a top-quality product.

Total Quality Management

It is the approach to achieve the goal to produce effective and efficient products by working on the ground level at every step and covers all the internal priorities of different departments. It works at the process level, where the main focus is to detect, identify and eliminate the errors in any area within the organization be it the manufacturing sector, supplying chain, or customer satisfaction. It aims to build customer satisfaction and showcase dedication and building commitment. Total quality service, Strategic quality management are some of the other names for Total Quality Management. 'Total' refers to everything and everyone in the organization involved in pursuing purity from raw materials to finished goods. Thus, it is often referred to as company-wide quality control (CWQC).

Relevance and Essentiality of Quality Management System in achieving Total Quality Management

➤ Customer satisfaction

This management system helps to develop an environment within the organization that revolves around customer satisfaction by having direct one on one interaction between customers and the employees about their requirements. This develops faith and customer compliance with the

How to cite this paper: Ms. Soumya Pathak | Ms. Swarnima Negi | Dr. Sachdev Yadav "Quality Management System: A Much-Needed Tool to Ensure Total Quality Management" Published in International Journal of Trend in Scientific Research and Development (ijtsrd), ISSN: 2456-6470, Volume-5 | Issue-3, April 2021, pp.784-787, URL: www.ijtsrd.com/papers/ijtsrd39975.pdf



IJTSRD39975

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organization and one step towards achieving the prime goal of customer satisfaction. On one hand, where total quality management resolves the problem internally by increasing the interaction between customer and employees, on the other hand, quality management system identifies if the employees need the training to do so and re-establish the preexisting procedures.

➤ **Increase effectiveness of the organization**

A quality product requires a well-planned and structured quality process to take the organization to the height of producing the product that fits into the frame which the customer has demanded. With the advancement in every field, the use of quality management software is the best solution to have a streamlined and consistent workflow. The software makes the job easy to follow the instructions and facilitates in producing good quality and customer compliance products.

➤ **Process Improvement**

The quality management system gives the flexibility to change the processes and procedures according to the need to improve the quality of the product. It guides through the change management system so that employees adapt properly to that whatsoever changes that have been made. A good management system makes the organization ahead in terms of producing good quality products.

➤ **Increase employees involvement**

The management system ensures that no employee within the organization work under pressure as it decreases productivity rather it gives them chance to express their ideas to help the organization grow positively. It gives them space and makes the working environment that everyone feels, they are liable to maintain the quality standards and customer requirements. Later to cross-check the QMS software validate the work done within different levels.

➤ **Improved decision making**

A good management system does not let the employees directly jump to conclusion and stops making any irrational decisions rather it has the provision to let the software analyze the data thoroughly and make decisions based on the data entered to it rather than opting for the old ways of searching the information on papers. Former is the better way to make the factually based decision.

➤ **Improve collaboration and communication**

The management system gives space and individuality to every employee to share and express their positive ideas for the improvement in the product quality. This environment boosts their morale and increases the communication between the employees so that they can collaborate and work towards the upliftment of the organization.

➤ **Continuous product improvement**

Philosophy of continuous, never-ending improvement achieved by efficient and smart working strategy. Continuous improvement includes all small, incremental improvements that should occur regularly which will eventually contribute to a vast improvement in the quality of the product.

Prerequisites of a Quality Management System

The sustainability of a QMS is based on the efficacy of the design with which it is been created. In today's highly competitive environment, organizations rush into the

market to succeed in the aspects of quality and customer satisfaction while making a profit for the organization. Four basic prerequisites are responsible to facilitate the organization to own staff commitment and customer satisfaction.

➤ **Statement of mission** - It defines the sole purpose of the organization to flourish in the market by providing the type of service or wishes to serve. The creation of the statement must involve every employee of the organization and must show dedication, commitment, and innovation to the work they are doing. The statement includes:

- The change at which the organization aims.
- A business statement
- A value statement that involves professional services.

➤ **Strategic plan** - It focuses on the plans designed by the intellectuals of the organization to manage the upcoming opportunities and related threats with respect to the organization's strengths and weaknesses. It deals with creating a vision and mission and strategies to meet the goals proactively.

➤ **Effective management skill** - The top management must demonstrate the value of the goals to its employees/staff and motivate them to genuinely believe in the value of the project simultaneously welcoming any innovations from them meanwhile providing them all the possible resources and team commitment.

➤ **Quality culture** - A culture is set by the norms, beliefs, and values towards a particular aspect. The senior employees must create a positive environment where the staff feels a sense of comfort ability in expressing their new innovative ideas and feels confident in their work and willing to take risks in the forthcoming time. This approach enhances the productivity of the organization, without compromising the quality of any product.

Processes involved in designing QMS

The type of process defines the activity to be carried out in designing an effective QMS model. These processes can broadly be classified as:

1. Core process

These are the main operational processes that leave a direct impact on the total management model and are responsible for attracting and retaining customers. This deals with the purchasing of the raw material to the delivery of the final product and the type of service being provided to the customers.

2. Support process

Information technologies have made human work easy thus, the technologies involved in conducting the core process constitute the support process. Therefore the support process does nothing but identifies and fulfill the requirements to facilitate the functioning of primary activities.

3. Management/ Assurance process

Execution of the operations involved in QMS is governed by the management processes. This also looks upon the financial performance as well as the effective and efficient service provided to the end-users.

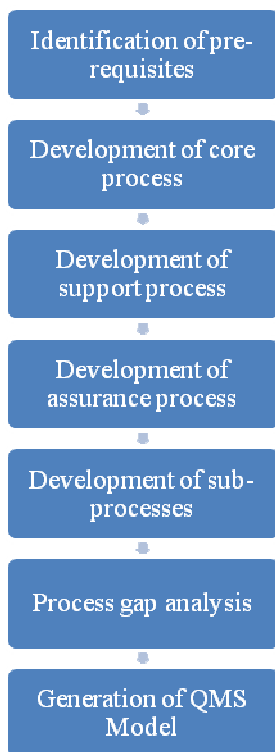


Figure 1 Process for designing a QMS

5. An effective monitoring and validation protocol to verify manufacturing models.

The PDCA cycle

The PDCA cycle is a systematic approach to a series of steps for continual improvement in process or product. It is an iterative four-step process typically used for a better strategy for developing a Quality Management System.

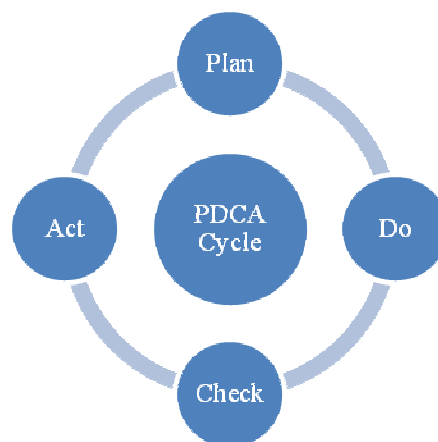


Figure 2 The PDCA Cycle of pharmaceutical quality management

Critical processes for developing the Quality Management System

➤ **Quality Planning**

Quality Planning is the key step to start a thread of managing quality at different levels. It is a structured process that involves manufacturing goods and services that meets customer needs and ensures their safety. It provides the main framework of events that need to be executed for designing methodology as it is associated with the several ideas, tools, techniques, and methods that demonstrate the performance of a product pertaining to its actual use. The first step is to identify customers and their needs and subsequently providing them requisite goods and services. The process design step also collaborates at this stage, the plans are made and implanted from the ground level and are made operational with the support of trained staff. Since there can be faults within the plans which are later tackled by already set up control systems to ensure quality at each level. The quality control system ensures that our quality performance is executed as planned. Good Quality Planning thus minimizes the final quality gap, the PDCA cycle is further embedded in the policy and procedure of an organization as a quality tool to enhance their performance.

➤ **Quality Control**

Quality control relies on five main basics: a limpid definition, a specific target, a clear goal to achieve, a sensor, an actual analytical way to measure the performance of the product in the market, a way to interpret the measurement and compare the achievement of target statistically and a way to take action, to make necessary changes and re-designing to process. The various aspects to implement a control strategy include the following:

1. Control of input materials (active drug substance, excipients, primary packing materials)
2. Product Specifications and quality impact.
3. Unit operations controlling the ultimate quality parameters of the final product.
4. In-process testing of intermediates and final product.

1. **Plan** - A thorough analysis of current issues is done by the working team to identify the root causes. Accordingly, appropriate solutions are then formulated to address them which corroborate both organization’s policy and customer needs.
2. **Do** - In this phase, the plan is implemented. The substantial improvement contrived in the planning step is brought to existence. The data is collected, unexpected observations are recorded and checked.
3. **Check/Study** - This step displays significant learning by actually observing the newly implemented process and plans. It provides an opportunity for a more comprehensive inspection and provides an enormous chance of process elevation.
4. **Act** - To attain a higher level of efficacy the cycle should be repeated. This may involve measuring and monitoring the benchmarks to ensure that improvements are maintained. If the changes made are not satisfactorily delivering the desired action, again the first step is followed and the team is suggested to address the potential solutions that were initially overlooked.

QMS documentation

Documentation is an integral part of any system. It is the value-adding activity that adds a series of benefits to the organization and helps to maintain consistency in the work. The documented data helps train new staff in the future and also gives the advantage to trace any faulty product or process. The documents that are used in QMS comprise different policy plans, procedure and work instruction or the SOPs, and the total record of the work done by the organization.

- **Manual** - It gives the information related to the quality management system of the organization to the customers, employees, shareholders, and suppliers.
- **Policy** - These are the statements that entail the working of the organization and dealing with the

different actions related to the business, services, etc. They are more likely the self-guiding principles that add to the decision-making capability of the firm.

- **Procedures** – It entails the implementation of the policy and the set of rules in the organization. It involves the purpose and scope of the particular document in any service. It has the information related to the roles and responsibilities of the people working in the organization and the associated documents required to complete to submit after any procedure. It has the details related to the resources needed in the particular procedure and the description of procedures in a detailed manner.
- **Working Procedure or SOPs** – They are the set of validated rules to carry out any task in the future to maintain consistency in the work and avoid the production of quality compromised products.
- **Records** – They are the evidence of the activities that are performed in the organization to achieve the top quality product. Maintaining records is also beneficial in the audits to get a clean chit and the top quality certification from the regulatory bodies itself which eventually builds the customer compliance and faith in the organization.

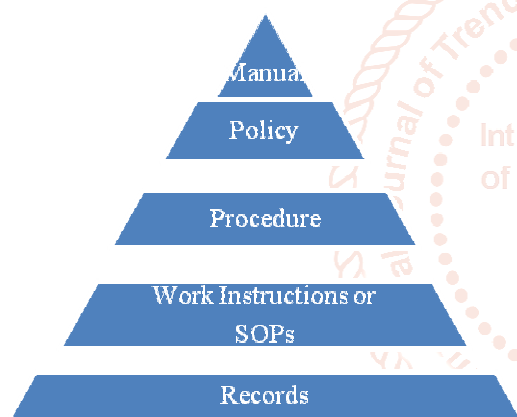


Figure 3 Hierarchy of QMS documentation

Conclusion

The quality management system along with the total quality management provides long-term success for the firm by fulfilling the patient requirements on a priority basis. The complete activity of management improves the quality of the product not just by polishing the image of the organization from the outside but also keeps a check of every single process and procedure within the organization. This is essential to build a reputation and a distinctive name in the cut-throat competition.

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