BAHRIA UNIVERSITY, (Karachi Campus)

Department of Software Engineering

Assignment 4 - Spring 2022

COURSE TITLE:	Engineering Management	COURSE CODE: **MGT-423**	
Class:	**BSE-IV (B)**	Shift: **Morning**	
Course Instructor:	**ENGR. TALHA BIN SAEED**	Time Allowed:	**2 Week**
Submission Date:	**16/06/2022**	Max. Marks:05	
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[CLO4: 5 Marks]

QUESTION #01

Evaluate the QMS (Quality Management System) process to establish a quality system among organizations.

Solution:

QMS consists of written and controlled guidelines and procedures that form a foundation for all procedures. An organized QMS ascertains the steps for key processes and forms methods in preventing failures in a timely manner. QMS is organized to protect the brand, organization processes, and the customers' interest.

Benefits :-

Implementation of quality management system should result in many long-term financial gains. Here is the list of few benefits of effective implementation of a QMS:

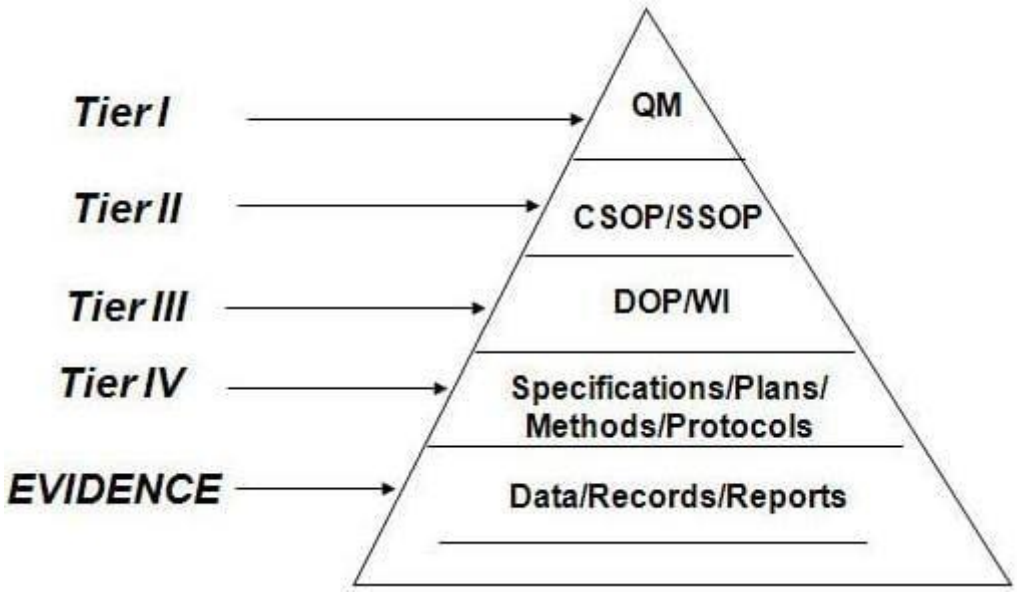
- Achieve organizational goals.
- Reduce costly errors.
- Improve customer satisfaction.

- Market your business more effectively.
- Manage growth more effectively.
- Improve documentation availability.
- Correct issues to improve products and services.
- Grow market share in new territories and market sectors.
- Creates a culture of quality.
- Embed vision for all projects.
- Better internal communications.
- Consistent products.
- Measure performance of individuals and teams.
- Improve compliance

The Importance of Hierarchical Organization

An organization is spirited when working with controlled documents. A suggested hierarchy for QMS documentation management is:

- Quality Manual
- Policies
- Procedures
- Work Instructions
- Lists
- Checklists
- Forms



Steps for the Creation of an Effective QMS

The steps required for the conceptualization and implementation of a QMS include the following:

1. Define and Map Your Processes

Process maps creation will force the organization to visualize and define their processes. In the process, they will define the interaction sequence of those processes. Process maps are vital for appreciating the responsible person. Define your main business process and converse the flow.

2. Define Your Quality Policy

Your Quality Policy communicates the duty of the organization as it is about the quality. The mission may be what customers need, a quality mission. When constructing quality management system, consider the commitment towards customer focus. It may be Quality, Customer Satisfaction, and Continuous Improvement.

3. Define Your Quality Objectives

All Quality management systems must have objectives. Each employee must appreciate their influence on quality. Quality objectives are derivative of your quality policy. It is measurable and set up throughout the organization.

The objective may be in the form of critical success factors. This helps an organization in emphasizing the journey towards accomplishing its mission. These performance-based measures deliver a gauge to determine compliance with its objectives.

Some Critical Success Factors are:

Financial Performance

Product Quality

Process Improvement

Customer Satisfaction

Market Share

Employee Satisfaction

4. Develop Metrics to Track and Monitor CSF Data

Once critical success factors are known, measurements and metrics keep track of advancement. This can be done through a data reporting procedure used to collect specific data. Share the processed information with leaders. A process goal is to enhance customer satisfaction index score. There needs to be a goal and a measure to establish achievement of that goal.

5. **Define Defects for Every Process**

Defects are non-conformances that happen as a product flaw or a process deficiency. Whenever a defect occurs it needs to be measured and corrected. Identify the required corrective action. When defining your defects:

Determine operation volume

Determine defects in product and process

Define a process to record defects

Define a process to report defects in specified formats

6. **Develop Documents and Records**

QMS needs to have some documented information and formats. Start with the minimum required document set and add when needed.

Create mandatory document information as per business model

Create essential Quality policies, procedures, and forms

Create documented information and formats (records) for each defined process

7. **Define Quality Process**

Your quality procedure includes internal audit, Management review, Corrective and preventive action process and communication processes.

8. **Determine Training Needs**

Everyone needs to exhibit competency in the job. Training is only the start and can happen on the job, it can be a classroom or e-learning. Some important training areas are- Internal auditor competence, Corrective Action training. Failure Modes Effects Analysis (FMEA) training.

9. **Use Quality Management System**

Using the QMS means producing the best quality product. In the process

Collect non-conformance and record them.

Review this data for corrective and preventive action.

Review FMEAs for risk and actions, as and when required.

Perform internal audits and conduct management reviews.

10. Measure, Monitor and implement activities to Improve the Performance

Using quality management system means collecting data. Analyze this data to check if the collected data is good to use and if the intended results can be derived. You need to:

Track Quality Objectives and its performance

Define few new performance yardsticks

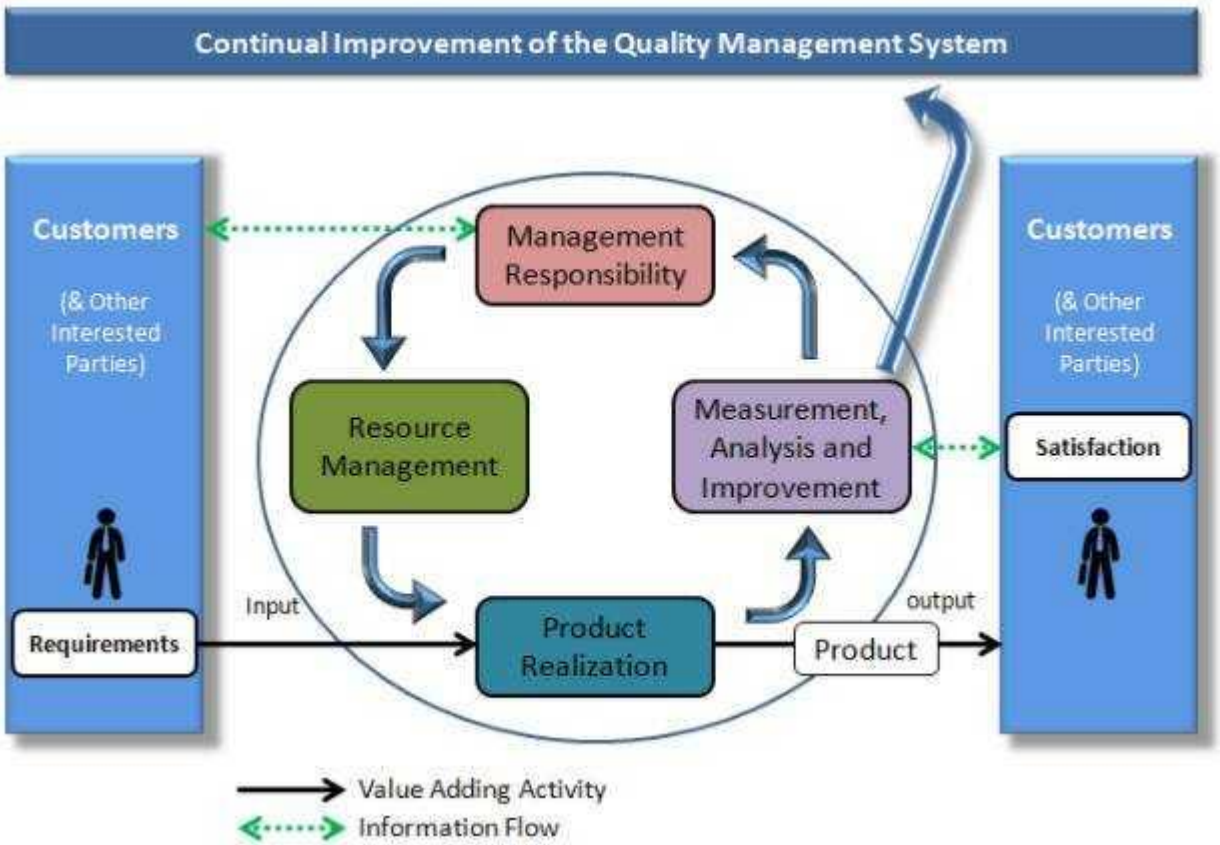
Determine improvement chances in the data by recognizing trends, patterns, or correlations.

If you have identified trends through data, then it is time to act. The goal is to bring improvement and this occurs by:

Arranging your improvement opportunities

Choosing prospects that make a difference

Supporting 'commitment to quality' to attain better results



The Role a Quality Management System Plays in a Life Sciences Company

The products created by pharmaceutical and medical device companies must go through a rigorous approval process, and part of that involves measuring their quality. The FDA, EMA, and other international regulatory agencies all have quality guidelines life sciences companies must follow, and many of them align with the guidelines laid out in ISO 9001 and ISO 13485.

Quality Management Standards

ISO 9001:2015 standard describes all the requirements that a company must meet to implement their own quality management system. By far ISO 9001:2015 is the most implemented and recognized QMS standard on the planet that counts for complete international acceptance.

However, there are plenty of other QMS standards available, such as the ISO 14000 family that deals with environmental management systems, the rest of the ISO 9000 family (including both ISO 9004 and ISO 9000), ISO/TS 16949 for QMS intended for automotive-related products, ISO 13485 for medical devices, and ISO 19011 for auditing management systems.

Conclusion

A product's quality can be measured in terms of durability, reliability, and performance. Quality is a crucial element that differentiates company from its competitors. By implementing proper quality management systems, you are ensuring that all necessary changes in your processes are implemented, which eventually leads to superior quality products and, in the end, bigger profits.