



Subject: **Quality Engineering**

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Overview *(Lecture the 2nd)*

- QMS
- QMS Elements
- Basic steps of QMS

QMS

QMS - is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organization's purpose and strategic direction

ISO 9001:2015 the international standard specifying requirements for quality management systems, is the most prominent approach to quality management systems

and **ISO 9004** – both are parts of **ISO 9000** family, priority is to achieve robust success in the organization processes

ISO 14000 - environmental management system

ISO 13485 - quality management systems for medical devices

ISO 19011 - auditing management systems

ISO / TS 16949 - quality management systems for automotive-related products

QMS

ELEMENTS AND REQUIREMENTS OF A QMS:

- * The organization's quality policy and quality objectives
- * Quality manual
- * Procedures, instructions, and records
- * Data management
- * Internal processes
- * Customer satisfaction from product quality
- * Improvement opportunities
- * Quality analysis

QMS

ESTABLISHING AND IMPLEMENTING A QMS

In order to help customer satisfaction before implementing QMS there is structure is based largely on the **Plan-Do-Check-Act (PDCA)** cycle and allows for continuous improvement to both the product and the QMS. The basic steps to implementing a quality management system are as follows:

- * Design
- * Build
- * Deploy
- * Control
- * Measure
- * Review
- * Improve



QMS

Design and Build

The design and build portions serve to develop the structure of a QMS, its processes, and plans for implementation. Senior management should oversee this portion to ensure the needs of the organization and the needs of its customers are a driving force behind the systems development.

Deploy

Deployment is best served in a granular fashion by breaking each process down into sub-processes, and educating staff on documentation, education, training tools, and metrics. Company intranets are increasingly being used to assist in the deployment of quality management systems.

Control and Measure

Control and measurement are two areas of establishing a QMS that are largely accomplished through routine, systematic audits of the quality management system. The specifics vary greatly from organization to organization depending on size, potential risk, and environmental impact.

Review and Improve

Review and improvement detail with how the results of an audit are handled. The goals are to determine the effectiveness and efficiency of each process toward its objectives, to communicate these findings to the employees, and to develop new best practices and processes based on the data collected during the audit.

QMS

The Plan–Do–Check–Act Procedure

- * **Plan:** Recognize an opportunity and plan a change.
- * **Do:** Test the change. Carry out a small-scale study.
- * **Check:** Review the test, analyze the results and identify what you've learned.
- * **Act:** Take action based on what you learned in the study step. If the change did not work, go through the cycle again with a different plan. If you were successful, incorporate what you learned from the test into wider changes. Use what you learned to plan new improvements, beginning the cycle again.