

ISO 9001 : 2015 - Quality Management System

Course Outline

1. Introduction to Quality Management System Auditing

- Overview of auditing principles and concepts
- Understanding the role and responsibilities of auditors
- Overview of ISO 9001:2015 and its application in auditing quality management systems

2. Auditing Fundamentals

- Types of audits and their objectives
- Audit planning, preparation, and execution
- Risk-based approach to auditing

3. ISO 9001:2015 Requirements

- Understanding the requirements of ISO 9001:2015
- Quality management principles and their application
- Process approach to quality management

4. Auditing Techniques and Methodologies

- Interviewing techniques and effective communication skills
- Document review and evidence gathering
- Sampling methods and data analysis techniques

5. Audit Process

- Audit initiation, scope determination, and planning
- Conducting on-site audits, including opening meetings, document review, and interviews
- Audit reporting, including non-conformity identification and reporting

6. Audit Reporting and Follow-up

- Preparation and issuance of audit reports
- Follow-up activities and verification of corrective actions
- Monitoring and measurement of audit program effectiveness
- ISO 19011:2011 and ISO 17021:2018

7. Audit Activities

- Audit Activities
- Identification of Non-Conformities [N/C's]
- Documenting the Audit (Audit Report)
- Conducting Audit Follow-Up
- Practical Auditing Exercise
- Competence and Evaluation of Auditors

8. Creating a Corrective Action Plan

- Who participates?
- Developing a Plan
- Using the Form
- What is Root Cause Analysis?
- When (and when not) to use Root Cause Analysis
- The Root Cause Analysis Process
- How to construct a Root Cause Analysis Checklist
- Examples of how a well-run Root Cause Analysis Process works
- Corrective and Preventive Actions

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