

ISO 9001 Quality Management System

Course Outline

Module 1: Definition and Fundamentals

- International Organisation for Standardisation (ISO)
- Introduction to ISO 9001
- Basic Terminology of Quality Management System (QMS)
- Principles of Quality Management System (QMS)
- ISO 9001 Family of Standards and Versions
- ISO 19011:2018
- Fundamentals of ISO 9001:2015

Module 2: Structure

- ISO 9001:2015 and its Clauses
- Process Approach
- PDCA Cycle
- Layout Standards that Follow the PDCA
- Scope and Limitations
- Limitations of ISO 9001
- Benefits of ISO 9001

Module 3: Internal Audit Structure

- Auditing Types, Procedures, and Planning
- Auditing Techniques
- Phases of an Audit
- Assessment of Audit Reports and Documents

Module 4: Internal Auditor

- Roles
- Responsibilities
- Leadership Skills

Module 5: Audit Programme

- Audit Programme
- Process Audit Checklist

Module 6: Audit Report

- Audit Reports
- Audit Findings
- Follow-Ups

Module 7: Procedures

- Procedures in Reference to the 9001:2015
- Scope of QMS
- Objectives of a QMS
- Policies of a QMS

Module 8: Methods to Operate a QMS Efficiently

- Challenges Faced During Implementation
- Methods to Operate a QMS Efficiently
- Implementation Process

Module 9: Risk Management

- Risk and Opportunity
- Risk-Based Thinking
- Conducting Risk Assessments
- Risk Assessment Methodology
- Risk Assessment Implementation
- Risk Register

Module 10: Roles and Responsibilities of a Lead Implementer and Quality Team

- Roles and Responsibilities of a Lead Implementer and Quality Team
- How to Maintain QMS Structure?
- Corrective Actions
- Records
- Sequential Operation Process
- Measurement and Monitoring of Processes
- Controlling of Errors

Module 11: Lead Auditor Training

- Roles and Responsibilities of a Lead Auditor
- Team Selection and Planning
- Lead Auditor Requirements, Scope, and Procedures
- Design and Development
- Tips for Lead Auditors
- Report Preparation, Findings, Reconciliation, and Conclusions

Module 12: Audit Activities and Techniques

- Opening Meetings
- Daily Discussion Meetings
- Closing Meeting
- Presentation of Reports
- Non-Conformance Report
- Tools and Techniques

Module 13: Methods of Collecting Information

- Visual Observation
- Examination of Records
- Employee Interviews

Module 14: Certification

- Certification Process for Organisations
- Selecting an ISO 9001 Registrar
- Steps to Certification

- Prepare for the Certification Audits
- Stage 1 Audit
- Stage 2 Audit
- Re-Certification Audit

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