



# ISO 9001: Principles of the Quality Management System (QMS)

## ISO 9001 Phase 1: Principles of the Quality Management System (QMS)

(Onsite – 2 Days, 16 Hours)

### Training Description:

This training will educate key process owners on the key characteristics, advantages, and impact of ISO 9001. The entire standard will be presented a section at a time for proper understanding of the requirements, and what is required of the company to achieve registration. In this training, participants will learn why ISO is needed, and what it means to be ISO registered. In addition, participants will learn about the benefits of being registered and how to maintain registration for long-term success and competitiveness. The participants will learn how to plan, implement, and review a Quality Management System and how to improve actions taken to meet its customer requirements. ISO 9001 Phase 1 is delivered in person, onsite for all levels of the company.

### Training Objective:

Upon completion of the training, each employee will have a comprehensive understanding of quality and continuous improvement along with the contents of ISO 9001. Most importantly they will understand how all their actions contribute to the bottom line of the company.

The following topics will be covered during the training:

- Why do we need ISO?
- What is the Process Approach?
- The 8 Quality Management Principles
- How the 5 major Clauses of ISO work as a process
- Why having a Vision, Mission and Quality Policy is important?
- Using the Plan-Do-Check-Act (PDCA) process to establish sustainable change and improvement
- Preparing for ISO registration

### Skill Attainment:

Participants will not only learn the skills that are necessary to perform in a company but will also gain lifelong experiences they can take with them in any future company they choose to join. ISO 9001 is a must for companies if they wish to work with major OEMs. Participants will receive a certificate for having completed the training from a registered lead assessor and trainer. This certificate will remain valid for as long as the standard remains in effect.

### Phase 1 (2 Days)

#### Principles of a Quality Management System - ISO 9001

What ISO is, and its origins.



What the ISO 9000 standard

Why ISO? How to get benefits from ISO9001.

ISO 9001:2015 clause explanation and requirements.

**Detailed review of the ISO standard. (Clause by clause review discussion/answer questions.)**

- Scope
- Normative references
- Terms & Definitions
- Context of the Organization
- Leadership
- Planning
- Support
- Operation
- Performance Evaluation
- Improvement

**PDCA (Plan-Do-Check-Act). How to properly implement ISO using PDCA model**

- **Plan:** Establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organizations policies
- **Do:** Implement the processes
- **Check:** Monitor and measure processes and product against policies, objectives and requirements for the product and report the results
- **Act:** Take actions to continually improve process performance

**Process Approach**

What it means to implement ISO as a process.

How to successfully implement multiple processes as a system.

**Discuss important concepts for implementing the new standard**

- Context of the Organization
- Strategic Planning
- Risk Based Thinking

**Explanation of Guidance documentation towards the understanding of:**

- Implementation Guidance for ISO 9001:2015
- Guidance on the requirements for Documented Information of ISO 9001:2015
- ISO Risk Based Thinking



## **ISO 9001 Phase 2: Development of the Quality Management System (Onsite – 5 Days, 40 Hours)**

### **Training Description:**

During this training, participants will learn how to properly document a Quality Management System via a quality manual (including the company's Quality Policy), procedures and flowcharts to ensure compliance with ISO 9001 requirements with the involvement from management. Document control process and customer satisfaction will also be covered during this training. Participants will also learn key processes involving customer support, manufacturing, purchasing, engineering, and others. Participants will be trained how to document their processes as required by the standard. ISO 9001 Phase 2 is taught with a mix of lecture and discussion. This training is delivered in person, onsite for all levels of the company.

### **Training Objective:**

Success will be measured by the successful completion of this module and having learned about:

- Management responsibilities
- Creating a Timeline and Project Plan
- More specific ISO/clause training as it pertains to each job type
- How to develop a Quality Manual, Procedures and Work Instruction
- How to set up a Documentation Control System that also helps to improve the efficiency of the documentation
- How to Flowchart company processes (Using Visio)
- How to use the Key Performance Indicators (Goals/Objectives) to measure processes We are a young company with many opportunities and becoming ISO registered will allow us to compete globally.

### **Skill Attainment:**

Participants will not only learn what is necessary for ISO but will learn how to develop a system for the long-term success of our company and any future organization they join by taking with them the ISO training.

### **Phase 2 (5 Days)**

#### **ISO 9001 Quality System Development**

Having learned about ISO, we will train towards the Development of an ISO compliant system by addressing specific items needed for registration and more importantly by the company for success. The items are, paced over time.

Discuss the components of ISO 9001. How to develop Documented Information that meets company needs, customer needs and ISO 9001.

#### **Documentation Required per ISO 9001:2015 (high level transversal documents)**

- Scope of QMS/Registration (4.3)
- Operation of Processes (4.4)
- Quality Policy (5.2.2)



- Quality Objectives (6.2.1)
- Control of Product and Service Provision (8.5.1)

**Discuss documents for the purpose of communicating the information necessary for the company to operate (low level, specific documents)**

- Maintain documented information (document control) (7.5)
- Retain documented information (records control) (7.5)
- Internal audits (9.2)
- Nonconforming outputs (8.7/10.2)
- Nonconformity and Corrective action (10.2)

Discuss a records control Matrix and offer example. (Record Matrix) Stress the importance of good / user friendly forms to record results

**Discuss other low-level documents per the standard required by the company**

- Management Review (9.3)
- Training (7.2/7.3)
- Sales / customer service (Contract Review process) (8.2)
- Design and Development (8.3)
- Purchasing (8.4)
- Calibration (7.1.5/7.1.5.1/7.1.5.2)
- Production Processes
  - Production
  - Storage
  - Shipping
  - Production forms
- Customer Satisfaction (9.1.2)
- Measurement of processes
- Measurement of product (i.e. inspections)
- Etc.

Learn how to prepare applicable forms. i.e. training matrix, calibration logs, Inspection forms, etc. based on the created procedures

Learn how to create other documents needed that will benefit the company Provide instruction on record retention for training and other important functions.

Work on responsibilities/authorities and methods for satisfying the standard. i.e., job descriptions, final org charts, etc.



## ISO 9001 Phase 3: Implementation of the QMS (Onsite – 4 Days, 32 Hours)

### Training Description:

In this Phase 3 Training, participants will learn the process of how to effectively implement a Quality Management System within a company. In addition, trainees will learn the critical components of effectively managing improvements and compliance of a Quality Management System. Participants will not only learn what is necessary for ISO but will learn how to implement a system for the long-term success of a company and any future organization they may join by taking with them the ISO learning. This training is a mix of discussion and lecture and hands on activities. ISO 9001 Phase 3 is delivered in person, onsite for all levels of the company.

### Training Objective:

Success will be measured by the successful completion of this module and having learned about:

- How to turn on the 'system' (Roll out of QMS)
- Understanding how the documentation applies to each job
- Why is training important, and how we determine if it has been effective
- How one fits into the Quality Policy
- How to manage and continually improve the QMS
- How to recognize compliance
- How to ensure that the major drivers i.e., Internal Audit, Corrective/Preventive Actions and the Management Review are corresponding

### Skill Attainment:

Participants will not only learn what is necessary for ISO but will learn how to implement a system for the long-term success of our company and any future organization they join by taking with them the ISO Learning.

### ISO 9001 Implementation of QMS Requirements

Learn to properly implement all Phase 2 items over training period in segments to assure success. Learn how to perform a Gap Analysis, Readiness Review to assure successful registration. Additionally, participants will learn:

- How to use the Context of the organization
- How to use Risk Based Thinking throughout
- How to use the created Documented Information
- How to turn on the 'system' (Roll out of QMS)
- Understanding how the documentation applies to each job
- Why is training important, and how we determine if it has been effective
- How one fits into the Quality Policy
- How to manage and continually improve the QMS



- How to recognize compliance
- How to ensure that the major drivers i.e. Risk Based thinking, Internal Audit, Corrective Actions and the Management Review used in improving the company's strategic direction

Prepare / Conduct a management review using the established procedure(s)

Develop an agenda template and discuss who should participate. What topics should be included for an effective management review will be covered such as:

- Status of actions from previous management reviews
- Changes in external and internal issues that are relevant to the quality management system
- Information on the performance and effectiveness of the quality management system, including trends in:
  - Customer satisfaction and feedback from relevant interested parties
  - The extent to which quality objectives have been met
  - Process performance and conformity of products and services
  - Nonconformities and corrective actions
  - Monitoring and measurement results
  - Audit results
  - Performance of external providers
- The adequacy of resources
- The effectiveness of actions taken to address risks and opportunities
- Opportunities for improvement
- Learn how to use the information by top management to assure
- Opportunities for improvement
- Any need for changes to the quality management system
- Resource needs

Training will address how to facilitate the meeting as organizing management.

Training on the use of suitable methods for monitoring and, where applicable, measurement of the quality management system processes.

How to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made.

Training on how to include data generated as a result of monitoring and measurement and from other relevant sources.

Learn how analysis of data provides information relating to:

- Conformity of products and services



- The degree of customer satisfaction
- The performance and effectiveness of the quality management system
- If planning has been implemented effectively
- The effectiveness of actions taken to address risks and opportunities
- The performance of external providers
- The need for improvements to the quality management system

Learn methods to continually improve the effectiveness of the quality management system

through the use of:

- The quality policy
- Quality objectives
- Audit results
- Analysis of data
- Corrective and preventive actions
- Management review



## ISO 9001 Phase 4: Internal Auditor Training (Onsite – 2 Days, 16 Hours)

### Training Description:

During this Phase 4 training, participants will learn that Internal Quality Audits are not performed just because it's a requirement for ISO, but that it can be a major driver for improvement within the company. A stronger company means more job stability, and growth opportunities for them. Participants will learn the skills necessary to conduct and complete internal quality audits. In addition, participants will learn how to develop Internal quality audit schedules, how to prepare for an audit, and audit plans with guidelines to address non-conformities, and most importantly how to document opportunities for improvement. ISO 9001 Phase 4 is a mix of discussion and hands on activities. This training is delivered in person, onsite for all levels of the company.

### Training Objective:

Success will be measured by the successful completion of this module and having learned about:

- Purpose of the Internal Quality Audit
- In-depth study of the ISO standard
- Characteristics of auditors
- How to develop an audit schedule
- How to prepare for the audits
- How to conduct interviews and perform audits
- Processing of the results for correction and or continuous improvement
- Finally, having learned to perform effective process audits

### Skill Attainment:

Participants will not only learn the skills that are necessary to perform internal audits in our company, but will also gain lifelong experiences that they can take with them in any future company they choose to join. ISO9001 is a must for companies if they wish to stay in business. Participants will receive a certificate for having completed the training from a registered lead assessor and trainer. This certificate will remain valid for as long as the standard remains in effect.

### Phase 4 (2 Days)

#### ISO 9001 Internal Auditor Training

#### Conduct Auditor Training:

The basis for this training is to perform ISO 19011 auditor training to help trainees develop their own internal capability to perform Internal Quality Audits as required per ISO9001:2015. The training will consist of:





- ISO9001:2015 Overview (Summary of key requirements that need to be audited)
- ISO19011:2002 Guidelines for Quality and/or environmental management systems auditing

**Preparing for the audit** - Planning, scheduling, audit team, preparation, checklists, etc.

**The audit** – Execution, Checklists and Audit techniques

**After the audit** – Closing meeting and reporting (Including CAPA's)

**Additional learning will result in:**

- Understanding of the Process Approach
- Identify the requirements of an auditor
- Form an audit team
- Plan, prepare and execute an audit
- Classify, record, and resolve nonconformities
- How to implement preventative measures to avoid future nonconformities

Trainees will conduct an Internal Audit using the methods learned under supervision for hands on training.

Discuss what you should expect at registration.

Discuss the various outcomes of an audit.

Quality policy

Goals and objectives

Review existence of minimum requirements for audit readiness by registrar.



## ISO 9001 Phase 5: All Employee Training of Quality Management System

(Delivered Onsite – 2 Hour Sessions/ 4 times or 8 Hours Total)

### Training Description:

This Phase 4 training will address how to apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. In addition, this training will cover how to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement can be made. Participants will learn how to include data generated because of monitoring and measurement and from other relevant sources, the 8 quality management principles, preparing for ISO registration etc. ISO 9001 Phase 4 is delivered in person, onsite with a mix of lecture and hands on activities for all levels of the company.

### Training Objective:

Upon completion of the training, each employee will have a comprehensive understanding of quality and continuous improvement along with the contents of ISO9001. Most importantly they will understand how all their actions contribute to the bottom line of the company.

- Why do we need ISO?
- What is the Process Approach?
- The 8 Quality Management Principles
- How the 5 major Clauses of ISO work as a process
- Why having a Vision, Mission and Quality Policy is important?
- Using the Plan-Do-Check-Act (PDCA) process to establish sustainable change and improvement
- Preparing for ISO registration
- ISO registration will open the opportunities for us to increase sales. We are a young company with many opportunities and becoming ISO registered will allow us to compete globally.

### Skill Attainment:

Participants will not only learn the skills that are necessary to perform in our company but will also gain lifelong experiences they can take with them in any future company they choose to join. ISO9001 is a must for companies if they wish to work with major OEMs. Participants will receive a certificate for having completed the training from a registered lead assessor and trainer. This certificate will remain valid for as long as the standard remains in effect.