



ISO 9001- Development of the Quality Management System (Onsite – 5 Days, 40 Hours)

Training Description:

Attendees will learn how to properly document a Quality Management System via a quality manual (including the company's Quality Policy), procedures and flowcharts – ensuring compliance with ISO9001 requirements with the involvement from management. Key processes from customer support to manufacturing, purchasing, engineering and others will be educated on how to document their processes as required by the standard.

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:

Employees 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 ISO9001:2015 (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.

Homework assignments

Homework between sessions will be assigned. The homework will be reviewed at the following session prior to starting a new session