Developing an AS 9100 Quality Management System

Phase 1 (2 Days)

Principles of a Quality Management System - AS9100

What ISO is, and its origins.
What the ISO 9000 standards are about.
Why ISO? How to get benefits from ISO9001. AS9100 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 AS9100:2015
- Guidance on the requirements for Documented Information of AS9100:2015
- ISO Risk Based Thinking

Phase 2 (6 Days)

AS9100 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 AS9100. How to develop Documented Information that meets company needs, customer needs and AS9100.

Documentation Required per ISO9001 (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)
- Operational risk Management (8.1.1)
- Configuration Management (8.1.2)
- Counterfeit Parts (8.1.4)

- Design and Development (8.3)
- Purchasing (8.4)
    - Purchasing Process
    - Purchasing Information
    - Verification of Purchased Product
- 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 or 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

Phase 3 (4 Days)
AS9100 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, 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; and

- 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 and
- management review.

Phase 4 (2 Days)
AS9100 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 AS9100 The training will consist of:

- AS9100 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.

Phase 5 (2 Days allocated - with small groups trained in 2 hour classes)
AS9100 QMS Training for All employees
AS9100 Overview

Inform/train remaining employees on what the quality management system is composed of, where the system documentation is located, how to get access to the documentation and how to use them for maximized benefit to the organization.
Learn methods for improving the system,
Learn how to be audited in an effective way by customers, registration bodies and internal auditors.
The training will address how to Apply 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.
How to include data generated as a result of monitoring and measurement and from other relevant sources.

How to analyze data / 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; and

The need for improvements to the quality management system. How 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 and
- management review.