ISO 9001 Executive Overview

What it is, and how to achieve it.
Executive Overview

► Who is ISO?
► What is a QMS?
► What are ISO 9000 and 9001?
► What are the Benefits of ISO 9001?
► What Does ISO 9001 Require You to Do?
► How Do We Implement ISO 9001?
► What are the Costs of Registration?
► How Long Does it Take to Implement?
► How do we begin?

In the following slides, the ISO 9001:2008 Standard is paraphrased for instructional purposes. Please Refer to the standard for the actual text.
Who is ISO?

♦ The International Organization for Standardization gathers industry professionals from 158 member countries to develop and improve standards.

♦ ISO authorizes organizations in each member country to manage the process of accrediting Registrars (ANAB, etc.)

♦ Registrars audit individual organizations and recommend them for certification.

♦ It is a 3 year certification
  ▶ Year 1 – Registration Audit
  ▶ Years 2 & 3 – Surveillance Audits
  ▶ (in addition to your internal audits performed constantly)
A quality management system (QMS) is a set of policies, processes and procedures required for planning and execution in the core business area of an organization. (Good business practices)

Core Areas - Areas that can impact the organization's ability to meet customer requirements:
- Quotations, Purchasing, Production, Shipping, etc.,
- Quality: Corrective/Preventive action of errors to achieve consistent results.

ISO 9001:2008 is an example of a Quality Management System.

Read more about a QMS and watch the Demo »
What is ISO 9000?

- ISO 9000 is a family of standards for a Quality Management System
- Read about ISO 9000 Family *(including obsolete standards ISO 9002 & ISO 9003)*
    - You will need to *buy a copy of the ISO 9001:2008 Requirements Standard*
- ISO 9000 is an internationally recognized QMS standard which acts as a quality benchmark when evaluating organizations.
- ISO 9000 Registration means you have a QMS in place to control your processes and deliver consistent results designed to meet the customer's requirements.
What is ISO 9001?

ISO 9001:

► Objective: customer satisfaction
► Is industry generic (anyone can use)
► Can be used by both manufacturing and service industries.
► Only tells you **WHAT** to do, not HOW to do it
► Is NOT a product standard – it contains no product requirements.

See free tutorial “Basics of ISO 9001” to learn more.
ISO 9001 is Based Upon Several Principles

You should understand these key items
(click each of the following to learn more):

► The Process Approach

► The PDCA model (Plan-Do-Check-Act)

► Eight Quality Management Principles

► Fundamentals of Auditing
Benefits of ISO 9001

External Benefits
♦ Improved consistency of service and product performance
♦ Higher customer satisfaction levels
♦ Improved customer perception
♦ Competitive advantages and increased marketing and sales opportunities.
  ▶ If you meet ISO 9001, a potential customer will know you have a solid QMS in place and likely have good quality.
  ▶ This could be a DECIDING FACTOR between you and your competition!

Internal Benefits
♦ Improved productivity and efficiency
♦ Cost reductions based upon reduced errors
♦ Improved communications, morale and job satisfaction

Read about ISO 9001 Benefits and download a free PowerPoint “Benefits of ISO 9001”
Requirements of ISO 9001
(click each of the following to learn more):

ISO 9001 has many requirements which can be summarized as:

♦ Determine the customer requirements

♦ Establish Quality Policy & Objectives and a work environment necessary to meet these requirements.

♦ Design and manage a system of inter-related processes to attain objectives. (QMS)

♦ Measure and analyze the effectiveness of each process in meeting goals and customer requirements. (Audits)

♦ Continually improve the Quality Management System

Download the ISO 9001 Requirements in Plain English
Requirements of ISO 9001

There are 8 sections in the ISO 9001:2008 Standard, summarized here:

- Scope
- References
- Terms and definitions
- Quality Management system (Documentation)
- Management responsibility (Commitment)
- Resource Management (People, Environment, etc.)
- Product realization (Production, or what you do)
- Measurement, Analysis and Improvement (Proof)

Sections 4, 5, 6, 7 & 8 contain the requirements and you will need to address each of them. Specifically...(next page)
Major Requirement Clauses of ISO 9001

(click each of the following to learn more):

♦ **Management Responsibility**
  - Commitment, Customer focus, Policy, Planning, Responsibility, Authority & Communication, Review

♦ **Resource Management**
  - Human Resources, Infrastructure, Work Environment

♦ **Product Realization**
  - Customer Requirements, Design, Purchasing, Operations, Calibration

♦ **Measurement and Analysis**
  - Customer Satisfaction, Audit, Process/Product Control, Non-conforming product, Data Analysis, Improvement
Required QMS Documentation

- **Quality Policy**
  - Your Organization’s Commitment to Quality

- **Quality Objectives**
  - Measurable Quality Goals which support the Policy

- **Quality Manual**
  - What you do to meet the standard

- **Procedures & Work Instructions**
  - Outlines steps referenced in the Quality Manual

- **Quality Records**
  - Records & Tables as evidence of QMS performance
Steps to ISO 9001 Certification
(click each of the following to learn more):

Your implementation plan should cover these items:

Learn and understand ISO 9001
  – Review ISO 9001 Standard and supporting materials

Perform a Gap Analysis
  – Evaluate your current quality system vs. ISO 9001

Plan your project and allocate resources
  – People, Money, Time, etc.

Train your organization
  – Management Rep, Project Team, Employees, etc.

Create & Document a QMS
  – Adding/revising processes

Use and Improve your QMS
  – Run your normal organizational activities following the QMS

Audit your QMS to ensure you meet objectives
  – Corrective and Preventive Action when addressing errors

Registration Audit of your QMS (3 year Certification)
  – Year 1 = Registration Audit
  – Year 2 & 3 Surveillance Audits
ISO 9001 Project Timeline

♦ Varies with Size & Complexity of Org.
  ► Many clients are between 3-6 months
  ► Depends on time and resources applied

♦ Create QMS
  ► From a few days to several months

♦ Use/Improve QMS & Internal Audit
  ► Usually 2+ months due to business cycle

♦ Registration Audit - 2 days
  ► Follow up to fix non-conformances

The 9000 Store provides several free ISO 9001 project timelines.
Costs of Registration
(Costs vary depending on size and complexity of organization)

♦ Creating QMS
  ➤ Use templates to save time
  ➤ Consultant: $5,000-$50,000

♦ Internal Auditing (No certification is required)
  ➤ Train Internal Team of Auditors In House $500
  ➤ Send to Internal Auditing Course ~$1200/person
  ➤ Hire 3rd Party ~$1000/day ± $400

♦ Costs of Registration Audit *(Click to contact a Registrar for a Quote)*
  ➤ Allowable audit times follow ISO 17021, but vary with Organization
  ➤ ~$1400/day ± $200, *PLUS travel expenses*
  ➤ Registration Audit: 2+ days
  ➤ Surveillance Audit: 1+ days
Where Do You Begin?
(click each of the following to learn more):

♦ Follow the 9000 Store **Project Manager’s Guide**
  ▶ Step by Step Guide to ISO 9001 Certification

♦ Buy **ISO 9001 Certification Package**, which includes:
  ▶ Gap Checklist Toolkit
  ▶ Complete QMS Documentation with Quality Manual, Procedures and Form Templates for all 20 requirements
  ▶ 2.5 Hour Project Team Training
  ▶ Employee Training for the Whole Company
  ▶ Internal Audit Training & Checklist

♦ The 9000 Store provides **Free Support** for the length of your project
  ▶ Call 877-942-6572
  ▶ Email questions for your entire project
  ▶ Online Resources

♦ **Registration** - We’ll help you find a Registrar
Simplify Your Certification Project

♦ Consult the ISO 9001:2008 Project Manager’s Guide for detailed step by step instructions

♦ The 9000 Store has helped thousands of organizations in more than 40 countries reach certification since 2001.

♦ We’re the original source for ISO 9001 solutions

♦ Can your organization afford to trust their quality to anything less than the best?