


# ISO 9001

## Implementation and Certification Checklist





Your ISO 9001 implementation can become more manageable by breaking it down into distinct tasks. This handy checklist reflects our proven simplified approach to ISO 9001 that focuses not only on easy, stress-free implementation but also on efficient, non-bureaucratic processes that truly benefit your business.

## Step 1

## Preparation



### Define Your Goals

Your organization can gain numerous internal and marketing benefits from ISO 9001 – if it first defines and then actively pursues them. Focus on operations and current shortcomings. Convert into SMART objectives.



### Define the Scope

You aren't required to apply ISO 9001 to your entire organization. Decide if any departments should be excluded. Decide on a gradual roll-out.



### Choose Your Implementation Approach

Do-It-Yourself kit, consultant, or a hybrid approach? Each could be done remotely.



### Assign Responsibilities

No matter which implementation approach you choose and which ISO tasks you outsource, somebody needs to be the ISO 9001 point person. If you do it all in-house, you might even appoint an implementation team.



### Learn the ISO 9001 Requirements

The ISO 9001 point person and the implementation team should have a solid understanding of the standard and its requirements. Some of this knowledge can also be acquired by working alongside a consultant.



### Gain Management Support

Don't take this lightly. It's crucial that top management not only support the ISO project but also "walk the talk". The first step in achieving active support is providing management with the needed knowledge.



### **Generate Employee Buy-In**

Inform your staff early and before rumors start. Show how employees will benefit from ISO 9001 and explain how everyone can contribute positively to the project.



### **Conduct a Gap Analysis**

A gap analysis prior to project planning is particularly useful for larger companies or if a consultant is involved. Small and mid-size companies could conduct several small gap analyses during the documentation or implementation phases.



### **Develop a Project Plan**

Plan the ISO 9001 implementation as a project. Focus on implementation steps, milestones, and target dates. Assign responsibilities. And keep it simple!

## **Step 2**

## **Documentation**



### **Start with the Document Control Procedure**

The ISO 9001:2015 standard includes explicit and implicit requirements for documents and records, as well as stringent document control guidelines. Since all (ISO 9001) documents must be controlled, it is wise to develop your document control procedure first.



### **Create the High-Level Documents**

These documents form the basis of your QMS: scope statement, quality policy, quality objectives, and process map.



### **Develop Your Procedures**

Take one clause at a time and determine the organizational functions that are impacted. Establish the current level of compliance and – together with affected management – work out how to fill the gaps.



### **Create Forms and Checklists**

Forms and checklists save time. They can support work processes and record keeping. Develop forms and checklists that simplify compliance with your procedures.

## Step 3

## Implementation



### Provide Manager Training

Teach department managers and team leaders how to use ISO to achieve tangible benefits. Then let this key group adopt an active role during implementation.



### Introduce the Procedures

Introduce staff to your new procedures, one at a time. Use employee meetings or teach managers to inform their staff. Start with document control.



### Achieve Process Improvement

Empower staff to redesign their work processes along the new ISO 9001 requirements. Processes are best analyzed and fine-tuned through flowcharts on a white board. Redesigned process should be documented.



### Have Staff Write Their Own Work Instructions

Work instructions are step-by-step directions on how to perform an activity. Work instructions are best written by staff who actually perform the work. You may need to verify compliance with your new procedures.



### Keep Records

As you are implementing new processes, be sure to generate and keep records. Certification auditors will use them to verify compliance.



### Market Your Upcoming Certification

Gain early marketing benefits through advertising your pending accreditation. Add substance by describing your QMS, summarizing your procedures, and announcing your certification date.

## Step 4

## Internal Audit



### Set Up the Audit Program

The audit program includes an audit schedule, methods for audit planning, auditing forms and checklists, and a team of auditors. A procedure is useful.



### Provide Auditor Training

Auditors need to be familiar with the ISO 9001:2015 standard, be able to verify if its requirements are effectively implemented, and have good auditing skills.



### **Support Your Implementation Through Audits**

Start your audits early to support your implementation efforts. Leverage your audits as a training tool. Initially, focus on particular requirements or procedures.



### **Conduct a Complete Audit**

Conclude one complete internal audit and ensure that any identified nonconformities are addressed prior to certification. Keep records.

## **Step 5**

## **Certification**



### **Select Your Registrar**

Choose an accredited registrar that meets your company's specific needs.



### **Prepare Company and Staff**

Tidy up work areas, and remove uncontrolled and obsolete documents. Prepare staff and rehearse typical auditor questions.



### **Pass the Certification Audit**

Undergo the stage 1 and stage 2 audits. Address any nonconformities and inform your registrar.



### **Market Your Certification**

Publicize your certification through press releases, your website and company stationary. Inform current and prospective customers.



### **Maintain Registration**

Make sure your QMS remains implemented and used in daily operations. Continue your internal audits. Have your registrar perform surveillance audits. Address any nonconformities.