

Project Manager's Guide



ISO 9001:2008 Implementation

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Introduction

This project manager's guide is designed to help you plan and manage your ISO 9001:2008 Project. The [Documented Quality System](#) includes a Quality Manual, Procedures and Forms for an ISO 9001:2008 Quality Management System.

All of the documents in the [Documented Quality System](#) are in Microsoft Word or Excel, and are very easy to edit. You will make this system your own by reviewing and editing the procedures, manual and forms. You will also be making changes to your existing processes so you meet the requirements of the ISO 9001:2008 Standard. This project plan will help you manage these changes.

The basic steps we recommend are:

1. The Project Manager completes the [Online Training Session](#).
2. The Project Manager prepares a Project Plan.
3. Management and the Project Manager identify an ISO 9001 Steering Team.
4. The Project Manager and others conduct a Gap Analysis with the [Gap Analysis Checklist](#).
5. The ISO 9001 Steering Team assign responsibilities for customizing each procedure to a team or individual.
6. Document measurable for each process.
7. Team leaders hold team meetings to revise processes and procedures based on the results of the Gap Analysis and the prepared [Procedures](#).
8. The Project Manager trains employees on ISO 9001:2008 using the [Training Materials Package](#).
9. The ISO 9001 Steering Team reviews the procedures as they are completed.
10. The Project Manager trains internal auditors using the [Internal Auditor Training](#)
11. The system is used for several months while records are collected and improvements are made.
12. The Registrar comes to audit.

This guide outlines these steps in more detail, and provides forms and templates to help you. This is a recommended plan, and you may change it to suit your organization.

Project Plan

A. Determine the project goals (Use the Project Plan Template in Appendix A)

In order to start planning, you will need to determine what your goals are for the project. Answer these questions:

1. When will you start your project?

Consider the start of your project as the date of the Gap Analysis. When will you be ready to conduct the Gap Analysis?

Recommended steps to be completed before conducting the Gap Analysis:

- a. Identify one or more people to conduct the Gap Analysis; it is helpful if they have some quality system experience or audit experience.
- b. Print the [Gap Analysis Checklist](#).
- c. Schedule the Gap Analysis, and communicate to all employees what is being done, and why. You will want to be able to make the employees comfortable with answering your auditor's questions. (The auditor is the person conducting the gap analysis. It may be an audit team or one individual)

2. When does your company want to have an ISO 9001:2008 certificate in hand?

The answer to this question will determine your timeline.

- a. The shorter time frame allowed for the project, the more resources the project will demand during implementation.
- b. It is important to know what your goal is because other dates will be determined by this information.
- c. Find out if there are company goals, are there clients that are requesting certification or other circumstances that will determine the date?
- d. Your date may be revised later. You will use this as a target date, and as we move along to the gap analysis and creating the task list you will be able to determine if the date is realistic. It will depend on what you currently have in place for your quality system, and how many resources you have available for the project.

B. Identify Project Responsibilities

It is important to determine who will be leading this project. Are you the person leading the charge? If so, you would be the project manager. You do not need to identify the management representative at this point. You will need to clarify who makes up "Top Management". The standard has requirements to be fulfilled by Top Management, and the sooner they are involved in this project the better.

1. Who is your project manager?
2. Who makes up Top Management at your organization?
3. Who should be on the ISO 9001 Steering Team? (This team will play an important role in planning, coordinating and providing resources for the ISO 9001 project. See Appendix B for team responsibilities.)

C. Begin to fill in the Project Timeline

1. When will you conduct your Gap Analysis and how long will it take to complete?
 - a. A Gap Analysis can typically take anywhere from 2 days to 5 days to perform. It will depend on the size of your organization, the number of auditors, the state of your current quality system and the experience of your auditors.
2. Assign responsibilities
 - a. This will take one or two meetings. The project manager and top management should be involved. Choose a date after the task list has been completed. You will use this information to assign responsibility. (See section 2 "Planning and Holding the Planning Meetings")
3. Target a date for Introductory training for all employees.
 - a. You will want your employees to be aware of the project, what will need to be done, who will be involved, and why you are implementing ISO 9001:2008. Choose a date that is after the meeting discussed above. That way you can decide if some people that will be involved in the project need more detailed training, and you can let employees know who will be working on the project. Use the [Training Materials Package](#) to conduct the training sessions.

Scheduling and Conducting the Gap Analysis

A. Schedule the Gap

1. Review the project plan:
 - a. Who did you identify to conduct the gap?
 - b. Schedule the [Gap Analysis](#), and communicate to all employees what is being done, and why. You will want to be able to make the employees comfortable with answering your auditor's questions.
 - c. You may want to consider sending out a newsletter to inform employees that the Gap will be performed, by whom, when and why the Gap is being performed.
2. The audit schedule
 - a. Determine if you will audit by process/procedure or by area of the facility. Our approach is usually to audit by area of the facility.
 - b. Divide the facility into manageable areas. Schedule time to audit each section of the standard that applies to the area.
 - c. If you are using an audit team, assign the team to cover the various areas of the facility.
 - d. Arrange your [Gap Analysis](#) checklists so each auditor will have the sections of the standard that are applicable in the areas they will cover.
 - e. Arrange your checklists so each auditor will have the sections of the standard that are applicable in the areas they will cover.

B. Conducting the Audit

1. Follow the schedule that you have prepared. Go into each area of the facility to evaluate the current quality system. Focus on what is in place, and what is not in place. Remind auditors that you are not focusing on compliance or non compliance to the current system, but on the design of the current system, and how it matches the ISO 9001:2008 requirements.
2. Take notes on what is in place, and what will need to be developed and changed. Take complete notes, reference documents and examples.

C. Reporting

1. Summarize the audit findings in the form of a task list. You will usually identify several categories of tasks.
 - Processes that comply with the standard and are documented.
 - Processes that comply with the standard and must be documented.
 - Processes that do not comply with the standard and must be redesigned.
 - Processes required by the standard that are not currently in place.

For each requirement (or set of requirements) of the standard you will want to identify the status of the current system. The ISO 9001 Steering Team will use this information as they assign responsibility and timelines to Teams. Teams will be assigned responsibility for development of a procedure.

The Planning Meetings

A. Planning your meeting

1. Determine who should attend. Include top management. Answer these questions:
 - a. Who will be able to decide which employees will be assigned tasks?
 - b. Will they know whether the employees' workload will be able to accommodate the assigned tasks?
 - c. Who is responsible for resources and can make resources available to the ISO 9001 project?
 - d. This group should continue meeting as the "ISO 9001 Steering Team"
2. Create an Agenda, items to include:
 - a. Explain the "Implementation Steps" to the group (see handout in Appendix B)
 - b. Discuss Responsibilities of the ISO 9001 Steering Team (see handout in Appendix B)
 - c. Assign the tasks to individuals or teams. (Use tables from Appendix B)
 - § Review the responsibilities to make sure that they are well dispersed, not assigned heavily to one group or one individual.
 - § For each team identify a team leader. It works very well to have a member of the ISO Steering Team as a leader for each of the Task Group teams. It provides good communication between the teams and the ISO Steering Team throughout the project.
 - d. Determine resources required for completion of the tasks.
 - § Will teams or individuals need assistance with other responsibilities during the ISO 9001 project?
 - § What kind of technical guidance will be needed to allow these teams or individuals to complete the tasks efficiently and effectively?
 1. Assistance from the management representative?
 2. Prepared materials?
 3. Special Training?
 - e. Assign dates to tasks. (Use table from Appendix B)
 - § Stagger start dates according to resources available.
 - § Determine which tasks you need to complete in the beginning to allow others to build on, for example: Management Responsibility. Complete the Quality Policy and Quality Goals as well as identifying key processes and their interrelation early on in the project.
 - § Estimate the amount of time needed to complete each task based on the amount of resources available to the task.

Holding Task Group Team Meetings

The team leader is responsible for scheduling the first team meeting according to the plan on the Gantt chart.

1. An agenda is provided in Appendix C:
 - a. Explain the “Implementation Steps” to the group (use the Task Group Team Handout in Appendix C)
 - b. Discuss Responsibilities of the ISO 9001 Steering Team (use the Task Group Team Handout in Appendix C)
 - c. Hand out the procedure that the team will be responsible for.
 - d. Hand out the section of the Gap Analysis that applies to the team.
 - e. Determine resources required for completion of the tasks.
 - § Will teams or individuals need assistance with other responsibilities during the ISO 9001 project?
 - § What kind of technical guidance will be needed to allow these teams or individuals to complete the tasks efficiently and effectively?
 1. Assistance from the management representative?
 2. Prepared materials?
 3. Special Training?
2. Assign dates to tasks from the Gap Analysis using the start and finish date on the Gantt chart. The team leader should print copies of the section of the Gap Analysis that are relevant to the team.
 - a. Explain to the team that the [Procedure](#) and your process must match. Some of your processes (the way you do things) will need to be changed to meet requirements of the standard, and parts of the procedure will need to be edited to accurately describe what you do.
 - b. List the requirements from the [Gap Analysis Checklist](#) that you are not currently meeting. These will need to be evaluated to determine if you will change your process to match the procedure, or alter your process to meet the standard and edit the procedure.
 - c. List the requirements from the [Gap Analysis Checklist](#) that you are meeting. Evaluate these against the procedure to see if edits are needed to the [Procedure](#), or if the process documented in the procedure will work better for you.
 - d. Schedule next meeting. During the next meetings you will work on the tasks that you have listed above.
 - e. Once the process has been determined the procedure will need to be finalized and sent for approval by the ISO 9001 Steering Team.

3. Discuss the Next agenda:

- f. Read [The Store Procedure](#) (Or for the team responsible for the quality manual read [The Store Quality Manual](#) and compare to current processes.
- g. Assign tasks for implementing changes in your processes and editing prepared procedure.
- h. Set next agenda
- i. Schedule next meeting

Project Plan: ISO 9001:2008

Project goals:

Start Date: _____

Target Registration Date: _____

Responsibilities:

Project Manager: _____

Management Representative: _____

Top Management: _____

ISO 9001:2008 Steering Team _____

Project timeline:

Step	Schedule Date	Completion Date
1. Gap Analysis		
2. Create Task List		
3. Assign Responsibilities		
4. Introductory Training		
5. Design and Implementation		
6. System Complete		
7. Registration Audit		
8. Certificate Received		

Planning Meeting Handouts

Agenda:

1. Review the “Implementation Steps” (see handout attached)
2. Discuss Responsibilities of the ISO 9001 Steering Team (see handout attached)
3. Assign individuals to teams for each task group. (Use tables from Appendix B)
4. Determine resources required for completion of the tasks.
 - a. Will teams or individuals need assistance with other responsibilities during the ISO 9001:2008 project?
 - b. What kind of technical guidance will be needed to allow these teams or individuals to complete the tasks efficiently and effectively?
 - § Assistance from the management representative?
 - § Prepared materials?
 - § Special Training?
5. Assign dates to tasks. (Use table from Appendix B)
 - a. Stagger start dates according to resources available.
 - b. Determine which tasks you need to complete in the beginning to allow others to build on, for example: Management Responsibility and Document Control should start early in the project. Complete the Quality Policy and Quality Goals as well as identifying key processes and their interrelation early on in the project.
 - c. Estimate the amount of time needed to complete each task based on the amount of resources available to the task. Refer to the [Gap Analysis](#) results to determine how much work each team has to complete.
6. Schedule employee training sessions using the [Training Materials Package](#)
 - a. All employees need training on the ISO 9001:2008 Standard. Providing the training early on in the project makes everyone aware of the projects and its goals.

*Keep minutes of all of the ISO 9001 Planning and Steering Team meetings. This helps demonstrate top management involvement in the development of the ISO 9001:2008 Quality Management System. Record attendees.

Implementation Steps

1. The team of people assigned responsibility will use the [The Store Procedures, Quality Manual](#) and [Forms](#) as a foundation for the process to address the requirements of the standard. The team will use the task list to identify what areas need changes to processes.
2. Each responsible team will evaluate the process presented in the procedure, determine if any changes are necessary for your organization, and make edits to the procedure and forms.
3. The team will finalize the procedure and send it to the ISO 9001 Steering Team for review and approval.
4. The team will train employees that are affected by or have responsibility for the procedure.
5. The employees will start following the documented process and maintaining records.

ISO 9001:2008 Steering Team Responsibilities

1. Identify team members for each procedure.
2. Assign target start date and completion date for each team.
3. Identify training needs for employees and schedule training sessions for ISO 9001:2008
4. Meet on a regular basis to evaluate progress, answer questions for the teams and evaluate resource needs for the implementation.
5. Review and approve procedures as they are finalized.
6. Evaluate and choose a Registrar

Task Assignments

Task Group	Team Members	Team Leader
Quality Manual		
Document Control		
Control of Quality Records		
Management Responsibility		
Competence, Awareness and Training		
Infrastructure		
Planning of Product Realization Processes		
Customer Related Processes		
Design and Development		
Purchasing		
Control of Production and Service Provision		
Identification and Traceability		
Customer Property		

Task Group	Team Members	Team Leader
Preservation of Product		
Control of Measuring and Monitoring Devices		
Monitoring, Measuring and Analysis of Customer Satisfaction		
Internal Audits		
Monitoring, Measuring and Analysis of Product and Realization Processes		
Control of Nonconforming Product		
Corrective Action and Preventive Action		

Project Gantt Chart

(Change headings to the Months you expect your project to run. Then identify when each team will start and stop, shade the time that each team will run)

Task Group	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9
Document Control									
Control of Quality Records									
Management Responsibility									
Competence, Awareness and Training									
Infrastructure									
Planning of Product Realization Processes									
Customer Related Processes									
Design and Development									
Purchasing									
Control of Production and Service Provision									
Identification and Traceability									
Customer Property									

*Appendix B
ISO 9001:2008 Planning Meeting*

Task Group	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9
Preservation of Product									
Control of Measuring and Monitoring Devices									
Monitoring, Measuring and Analysis of Customer Satisfaction									
Internal Audits									
Monitoring, Measuring and Analysis of Product and Realization Processes									
Control of Nonconforming Product									
Corrective Action and Preventive Action									

Task Group Meeting

Agenda:

1. Review the “Implementation Steps” to the group
2. Review Responsibilities of the ISO 9001:2008 Steering Team
3. Review procedure that the team will be responsible for.
4. Review the section of the [Gap Analysis](#) that applies to the team.
5. Determine resources required for completion of the tasks.
 - a. Will the team need assistance with other responsibilities during the ISO 9001:2008 project?
 - b. What kind of technical guidance will be needed to allow the team to complete the tasks efficiently and effectively?
 1. Assistance from the management representative?
 2. Prepared materials?
 3. Special Training?
6. Assign dates to tasks from [Gap Analysis](#) using the start and finish date on the Gantt chart.
7. Schedule next meeting.
8. Next agenda:
 1. Read [The Store Procedure](#) and compare to current processes.
 2. Assign tasks for implementing changes in your processes and editing prepared procedure.

Implementation Steps

1. The team assigned responsibility for each procedure will use the [The Store Procedure](#) as a foundation for the process to address the requirements of the standard. The team will use the task list to identify what areas need changes to processes.
2. Each responsible team will evaluate the process presented in the procedure, determine if any changes are necessary for your organization, and make edits to the procedure and forms.
3. The team will finalize the procedure and send it to the ISO 9001:2008 Steering Team for review and approval.
4. The team will train employees that are affected by or have responsibility for the procedure.
5. The employees will start following the documented process and maintaining records.

ISO 9001:2008 Steering Team Responsibilities

1. Identify team members for each procedure.
2. Assign target start date and completion date for each team.
3. Identify training needs for employees and schedule training sessions:
 - a. Employee Introduction to ISO 9001:2008 using the [Training Materials Package](#)
 - b. Internal Auditor Training using the [Internal Auditor Training Materials Package](#)
4. Meet on a regular basis to evaluate progress, answer questions for the teams and evaluate resource needs for the implementation.
5. Review and approve procedures as they are finalized.