

ISO 9001 Implementation Techniques, Tips and Common Setbacks

1. Establish Commitment

Implementation takes time and resources. Make sure you have commitment before starting the project.

Tips:

Know why you are implementing ISO 9001. Is it because a client or market is asking you to register? Is it for the internal benefits?

Is the motivation coming from executive management?

Keep the reasons for implementation visible during your project to retain commitment and stay focused on the end goal.

Assign an ISO Steering Team. This team should be made up of management from the different areas of the facility. Include the Management Representative and people that have the authority to devote resources to the project and remove roadblocks.

Common Setbacks:

Assigning responsibility for implementation to one person or department:

The ISO 9001 Quality Management System is a Management System.

It is not a quality control program, and cannot be implemented by Quality Assurance alone.

Losing commitment during the project:

During implementation other projects come up that compete for people's time and resources. Ask decision makers if ISO implementation is still a goal.

2. Prepare an implementation plan and timeline

A good project plan is a key part of a successful project.

Tips:

Conduct a Gap Analysis. Compare your current system to the requirements of the standard. Determine what is already in place, and what needs to be implemented. From this you can prepare a task list for each of the sections of the standard.

Have the ISO Steering team create "Point Teams" for each of the sections that apply to your organization.

Determine team membership and the timeline for each team. Use information from the Gap Analysis and task lists to determine the appropriate people for the team, and estimate the timeline.

Common Setbacks:

Proceeding without a plan. Without a plan projects tend to run indefinitely, without showing measurable progress. By having a plan you have specific deadlines to meet. You can show progress as you meet the deadlines and take action if you are not meeting deadlines.

Not having the ISO Steering team approve and support the plan. The ISO Steering team will be watching the timeline, coordinating and implementing the plan. They should have input and approval of the plan, or better yet, prepares the plan.

3. Kick-Off the Project in a Big Way

Let everyone in the company know you have started your project. Hold the basic ISO 9001 training sessions for all employees.

Tips:

Include some sort of celebration in the kick-off. Examples include: a lunch for employees, a picnic, prizes or a cake.

Use this training and celebration to inform employees of the Plan and Timeline.

Tell employees how they will be involved and how they will be affected by the project.

Communicate why this will be good for the company and good for the employees.

Common Setbacks:

No Kick off. Employees that are working on the project are aware, but others in the company are not. When the new procedures are implemented employees do not know why, and there is little support for the ISO project. Nonconformances are common place in this environment.

Training on ISO 9001, but no information on why the company is doing this, or how employees will be involved. This can result in the employees thinking: Another management program, how long will this one last?

4. Design and Document the Quality Management System

Use information from the Gap Analysis and Project Plan. Use people currently involved in each process to make changes to the existing process and bring it into compliance with the standard.

Tips:

Use the ISO Steering Team and the Point Teams for the Design and Documentation. The ISO Steering Team meets on a regular basis. During these meetings the team reviews the timeline, reviews what the Point teams are working on, removes roadblocks, resolves conflicts and reassigns resources as needed to keep the project on track.

The Point Teams meet on an as needed basis according to the timeline. When the Point Teams meet, they address the tasks on their task list.

Spread out the Point Teams on the timeline so you do not have too many meeting at one time. For example, you may want to have the document control team meet early in the project to establish a system to collect and control the documents that will be generated, but the Internal Audit team would meet later in the process because audits will not begin until the system is complete.

Keep the Point Teams on schedule. Review their task list at the ISO Steering Team Meetings. Watch for problems and delays, and give them help as soon as problems arise.

Have each member of the ISO Steering Team Lead several Point Teams. Each Point Team should have an ISO Steering Team Member for a leader. This allows you to coordinate the work of the different teams.

Common Setbacks:

Poor team make-up. Make sure to include people involved in the process. For example, use purchasing staff for the purchasing team.

Not meeting timelines. Establish realistic timelines for the plan; teams should be able to meet them with small changes. If the teams are not expected to meet deadlines, other tasks will take precedence; the project will drag on and lose energy.

Misinterpretation of the standard. If you do not understand what is required by the standard you may waste time and resources doing things that are not required, frustrate team members, and miss important requirements of the standard.

No central point of collection and control of the new documents. If the document control system is not developed early-on in the project you create confusion on what documents are final, what has been approved, what is the final revision, where is the electronic file, was it distributed.

Not establishing document templates early on in the process. If you do not format and distribute document templates for procedures and work instructions you will not get consistent documents. You will need to go back at the end of your project and redo documentation.

Lack of communication during the project. Remember, employees that are not on Point Teams may not be hearing much about what is going on with the project. Employees may think the project has faded away. Communicate with newsletters, bulletin boards or meetings.

5. Run the System for Three Months

Once the system is complete, follow documented procedure, conduct internal audits and management review, and make improvements to the system.

Tips:

Start off with an additional training for all employees. Summarize the new quality system emphasizing their responsibilities. Review the timeline for running the system and conducting audits. Let everyone know when the registration audit is scheduled.

Schedule internal audits so you can audit the entire system two times before the registration audit. This allows you to find nonconformances and fix them before your registrar comes in.

Hold management review at least once before your audit (required). More is better.

Keep Corrective Actions on schedule!

Common Setbacks:

Lack of communication to employees. Employees that have not been involved in the design and documentation of the quality system will not be as aware of the requirements of the quality system. Training and communication are critical to get them involved.

Lack of follow through on corrective actions. The new system will generate numerous corrective actions. If they are not investigated and completed your system will not be ready for a registration audit.

Ineffective management review. Management must take a close look at data from the quality system, evaluate it and take action.