ISO 9001:2008 Gap Analysis Checklist

Summary

The gap analysis checklist compares your quality management system to ISO 9001, and tells you where you need to make the appropriate changes in your organization to meet ISO 9001.

- Read: what is an ISO 9001 Gap analysis for more information
- This checklist covers all the ISO 9001 requirements to help you identify and understand them
- This list is a tool to help you organize your gap analysis, and to evaluate results of the gap.
- Each question will determine if you:
  - Already comply to ISO 9001
    - You do not need to change anything
  - Have a similar process, but don't fully comply
    - Revise process, training people on changes, audit to ensure compliance
  - Do not have this requirement addresses
    - Create a process based upon ISO 9001 requirement
- Use a copy of the **ISO 9001:2008 Standard** along with this checklist and you will be able to understand what the standard requires of your organization and better evaluate your system against the actual requirements.

Throughout this document, you will find the following helpful tools:

- Links to supporting information are underlined blue text
- Links to buy Standards directly from the source (TechStreet) are **Underlined Bold Red text**

Learn about ISO 9001:2008

Here are links to helpful information to help you understand ISO 9001:

- ISO 9001 FAQ
- Who is ISO?
- What is ISO 9001?
  - **Buy ISO 9001:2008**
  - Review the Requirements of ISO 9001:2008
  - Learn changes from ISO 9001:2000 to ISO 9001:2008
- What is a Process Approach?
- What is a Quality Management System?
- ISO 9000 (2005) Fundamentals & Vocabulary for ISO 9000 Standards
  - Learn about the ISO 9000 Standard
  - **Buy ISO 9000:2005**
- ISO 9000 Supporting Standards (Auditing, Industry Specific Guidance, etc.)

Steps to perform Gap Analysis

1. Prepared your audit schedule,
2. Assigned responsibility to your auditors for different areas or processes to audit
3. Copy each section of the checklist for the auditors working with that section.
4. As you work through the checklist
    a. Identify the areas that need to be developed for the I.
    b. Make reference procedures or other documents that you have and that will provide information for the new QMS.
    c. Take notes on the status of the documents:
        i. will they need to be revised for the new system?
        ii. Or can they be used as is?
        iii. Also note where processes are in place, but documentation is needed.

Focus on what is in place, and what needs to be developed. While you do want to know if procedures and processes are being complied with, **compliance is not your main objective for this audit**. ***Remember that the final outcome of this audit should be a list of things that your organization needs to do to comply with ISO 9001:2008.***

Help Preparing for ISO 9001 Certification

We offer several other tools to help your organization transition to ISO 9001: 2008.

- ISO 9001 QMS –
    - Complete Quality Manual, Procedures, Forms and Flowcharts
- ISO 9001 Project Implementation Training
    -
- Employee Training – PC based training which can be taken via the web.
    - It can be customized to give you better record keeping and automated deployment.
- PowerPoints - reviewing clause by clause review of ISO 9001
- Audit Checklist - to help you audit to the Standard
- Internal Auditor Training – which includes the materials to train your auditors on the standard.
- Problem Solving Training
    - Root Cause Analysis with Corrective Action
    - Mapping Work Flows
    - 6 Sigma, Lean & More.

ISO 9001 All in One Documentation and Training Package has everything you need to prepare for certification.

4 QUALITY MANAGEMENT SYSTEM

	REQUIREMENTS	CURRENTLY IN PLACE (List documents or evidence)	COMPLIANT Y/N? Estimated % Complete	ITEMS NEEDED
4.1	**General Requirements**			
This clause asks you to identify how management applies the process approach to achieve the effective and efficient control of processes, resulting in performance improvement. Specifically this section is looking for an overall process evaluation of all quality related processes and their interrelationships. Look to see that your organizational processes are defined and that consideration is given to those items described in a) through f).				
	a) Look for documentation of the processes included in the QMS			
	b) Look for information on the relationship and sequence of the QMS processes.			
	c) Ask Management if operation and control of processes is effective. How do they know if it is effective?			
	d) Ask how they are able to know if resources and information needed to support processes have been provided.			
	e) Is there any information on the effectiveness of processes?			
	f) How are improvements made to processes?			
	▪ What processes does your organization outsource? How is the process controlled?			

4.2	**Documentation Requirements**			
This section addresses how you use documents and records to support effective and efficient operation of your organization. A review of your procedures, work instructions, and records will determine if the standard requirements are met.				
	General			
	Does your quality system documentation include the documentation required by the standard?			
	a) Is there a list or other means of identifying other documentation required by your QMS? Are the required documents available?			
	b) Does the QMS documentation include Quality Records?			
4.2.2	**Quality Manual**			
	Review the Quality Manual if available.			
	a) What is the scope of your QMS?			
	b) What processes have been excluded? Is this appropriate?			
	c) Is a description or illustration of the interrelation of the processes included?			