



Global
Standards™

ISO 9001

**Quality Management Systems
Gap Analysis**

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ISO 9001 Gap Analysis

If you're currently implementing a Quality Management System (QMS) and aiming for ISO 9001 certification, this Gap Analysis will help you understand how compliant you are and where you need to do more work.

If you haven't done so already, you should familiarise yourself with the brief, plain English [Guide to the Requirements of ISO 9001](#) available for free from the Alcumus website. It gives a simple summary of all the major clauses.

The ISO 9001 standard, like many ISO standards, includes repetition, reinforcement of clauses within other clauses and jumping from one clause to another. So, whilst this document is sequenced in the order of the clauses, some sections bring in elements from other clauses and some sub-clauses are skipped when they've been included elsewhere. The aim here is to help you audit in an organised way that largely reflects the standard but which is logical and understandable. It helps you look at the system as a whole - which is the way an Auditor will carry out the formal audit.

This document is not a complete checklist of everything that's covered in the ISO 9001 standard (which you need a copy of and which you need to be familiar with). Being able to tick 'Yes' to all the sections in here is no guarantee that you will achieve ISO 9001 certification. However, it's a very good starting point if you're new to ISO 9001 and it can help form the basis of your internal audits.

The document starts with Clause 4 since the first three clauses do not contain auditable requirements.

Text in blue italics indicates tips from the ISOQAR Auditors.

Please note that this document is for your own internal use only and has no official standing.

Clause 4 - Context of the Organisation

This clause requires that you determine the relevant external and internal conditions that may affect your organisation's existence and strategy. The 'context' relates to the business environment in which you operate.

| Clause | Plain English Description | Yes | No | Gap Identified/Corrective Action Required | Owner | Target Date | Date Completed |
|--------|---|-----|----|---|-------|-------------|----------------|
| 4.1 | Identified the external and internal issues that affect the organization and the QMS. <i>Possibly written down e.g. as a SWOT analysis. If not, must be able to explain your awareness to the Auditor. Don't forget to include 'legal requirements'.</i> | | | | | | |
| 4.2 | Clear understanding of needs and expectations of interested parties, including customers and other stakeholders. <i>e.g. customer surveys.</i> | | | | | | |
| 4.3 | Scope of the QMS clearly determined. <i>The scope of your QMS must be written down. It should describe the type of products and services you offer and justify if any requirement of the standard is not applicable to you.</i> | | | | | | |

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|--------|---|-----|----|---|-------|-------------|----------------|
| 4.4 | The QMS is built and maintained in its entirety. You need to demonstrate an understanding of how you maintain and continually improve your system. | | | | | | |
| | Required resources are identified. | | | | | | |
| | Effective monitoring systems in place. | | | | | | |
| | Responsibilities assigned. | | | | | | |
| | Risks and opportunities identified and addressed. | | | | | | |
| | Systems to ensure processes achieve their intended results. | | | | | | |
| | Documented information to support processes and operation of system where necessary and to give confidence to staff (and Auditor) that processes are performed as planned. <i>Level of documentation only needs to be proportionate - take advice on this.</i> | | | | | | |

Clause 5 - Leadership and Commitment

Top management cannot delegate overall responsibility for the QMS. They have to take ultimate responsibility and show real leadership, taking a proactive, hands-on role.

| Clause | Plain English Description | Yes | No | Gap Identified/Corrective Action Required | Owner | Target Date | Date Completed |
|--------|--|-----|----|---|-------|-------------|----------------|
| 5.1 | Top management able to provide evidence that they take accountability for the QMS. <i>Able to answer questions, perhaps show minutes of meetings, have awareness of any improvement actions required.</i> | | | | | | |
| | Evidence that top management actively promote the QMS amongst staff. <i>Auditors might ask random staff for their comments.</i> | | | | | | |
| | Resources (staff, time, budget etc.) are made available where necessary to support the functioning of the QMS. | | | | | | |
| | Ensuring that the QMS achieves intended results. <i>Evidence from Internal Audits, Management Reviews etc. will help support this.</i> | | | | | | |
| 5.1.2 | The organization is aware of, and understands, both customer and statutory/legal requirements. <i>Evidence of contracts, specifications etc.</i> | | | | | | |
| | Understand the risks and opportunities relating to customer satisfaction - and that they are addressed. <i>There should also be emphasis on continual improvement. See also 10.3.</i> | | | | | | |
| | Emphasis on enhancing customer satisfaction. <i>See also 4.2.</i> | | | | | | |

Clause 5 - Leadership and Commitment

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|--------|--|-----|----|---|-------|-------------|----------------|
| 5.2 | <p>Quality policy should be relevant to your organisation and what you're trying to achieve. Should be documented and available to everyone.</p> <p><i>Should be visible to staff on noticeboard/intranet, for example, and people should be familiar with it. This should be relatively easy since you know your organization well.</i></p> | | | | | | |
| 5.3 | <p>Responsibilities and levels of authority for individuals relating to the QMS must be understood.</p> <p><i>A good way to check this is by random questioning of staff.</i></p> | | | | | | |

Clause 6 - Planning

Risk-based thinking is one of the cornerstones of ISO 9001. This is all about ensuring that the expected results are achieved, and no unwanted incidents occur.

| Clause | Plain English Description | Yes | No | Gap Identified/Corrective Action Required | Owner | Target Date | Date Completed |
|--------|---|-----|----|---|-------|-------------|----------------|
| 6.1 | With reference to 4.1 and 4.2, be sure that the QMS can reduce/prevent undesirable effects and support continual improvement. Make sure you have actions identified to address these risks and opportunities. <i>This is one of the main purposes of a QMS, supporting the aim of continual improvement.</i> | | | | | | |
| | Systems to evaluate the effectiveness of actions you take. <i>This is connected to clause 9.</i> | | | | | | |
| 6.2 | Have in place quality objectives relating to relevant functions/processes that support the QMS which are measurable, monitored and communicated. <i>Important objectives should be documented. It's important to consider how and when objectives will be achieved and when and who is responsible.</i> | | | | | | |
| 6.3 | When making changes, think about their purpose, possible consequences and how to implement them. <i>This relates strongly to 4.4.</i> | | | | | | |

Clause 7 - Support

The organisation is required to establish and maintain the necessary infrastructure to ensure operation and compliance with product and performance.

| Clause | Plain English Description | Yes | No | Gap Identified/Corrective Action Required | Owner | Target Date | Date Completed |
|--------|--|-----|----|---|-------|-------------|----------------|
| 7.1 | Determined and provided the resources (people, budget, infrastructure, tools, IT etc.) to support the ongoing running of the QMS. <i>You should be able to explain to the Auditor how you did this.</i> | | | | | | |
| | If 'measurement' is essential as evidence of conformity of products and services, evidence of how you calibrate tools/ systems to verify results and prevent deterioration. <i>You'll need documented evidence of measurements.</i> | | | | | | |
| | The organisation has the knowledge necessary to achieve conformity of products and services. <i>For example, gathering knowledge on your sector, on your customers. Consider lessons learned from Internal Audits/ corrective action for nonconformities.</i> | | | | | | |
| 7.2 | Individuals are competent and records are kept as evidence. <i>Relates to skills and experience of individuals. Consider training plans, certificates etc.</i> | | | | | | |
| 7.3 | Individuals are aware of the QMS, relevant quality objectives and their role. <i>They should be able to answer questions put by the Auditor.</i> | | | | | | |

Clause 7 - Support

The organisation is required to establish and maintain the necessary infrastructure to ensure operation and compliance with product and performance.

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| 7.4 | The organisation must determine what to communicate with regard to the QMS (internal and external) e.g. what, to whom, how, when. <i>It may be as simple as a statement on your website.</i> | | | | | | |
| 7.5 | The level of documented information required for effective running of the QMS has been considered and created. | | | | | | |
| | Systems of control for updating documented information are in place. Must also be adequately protected, accessible and retained. <i>Don't forget to include relevant documentation from external sources.</i> | | | | | | |

Clause 8 - Operation

This is the 'Do' part of the Plan-Do-Check-Act (PDCA) cycle and is the day-to-day part of what your organisation does. This clause is at the very heart of the of the Quality Management System.

| Clause | Plain English Description | Yes | No | Gap Identified/Corrective Action Required | Owner | Target Date | Date Completed |
|--------|---|-----|----|---|-------|-------------|----------------|
| 8.1 | Clear understanding of what the QMS is required to do for provision of products and services. <i>Need to be able to demonstrate your knowledge to the Auditor.</i> | | | | | | |
| | Planned the resources necessary. <i>Maybe something as simple as rotas, stock checklists etc.</i> | | | | | | |
| | Documents retained as required to demonstrate processes carried out as planned and conformity to requirements. <i>So you can provide evidence to the Auditor.</i> | | | | | | |
| | Process for controlling planned changes and to mitigate adverse effects. | | | | | | |
| 8.2 | Defined process for communicating with customers regarding: product/service information; contracts; inquiries/orders; feedback/complaints; handling customer property. <i>Generally, demonstrate you are committed to timely, accurate and proactive liaison with customers.</i> | | | | | | |
| | Process for determining the requirements for products/services to ensure it meets customer requirements and statutory/regulatory requirements. | | | | | | |
| | Process for handling changes in requirements. | | | | | | |

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|--------|--|-----|----|---|-------|-------------|----------------|
| 8.3 | <p>If you design/develop products/ services, are all aspects of 8.3 of the standard covered?</p> <p><i>Refer to the list in the standard, particularly 8.3.2 to 8.3.6. Remember this clause refers to design and development of services, not just products.</i></p> | | | | | | |
| 8.4 | <p>Ensure that externally provided processes, products, and services conform to specified requirements. This involves having criteria for the evaluation, selection, monitoring of providers.</p> <p><i>This applies to everything you purchase - not just elements of your service that you subcontract out.</i></p> | | | | | | |
| | <p>Have effective controls in place over outsourced processes. This needs to be demonstrated with documentation which should also show you can measure how customer requirements are being met.</p> <p><i>Services/products sourced externally are still within your QMS - they are still your responsibility.</i></p> | | | | | | |

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|--------|--|-----|----|---|-------|-------------|----------------|
| 8.3 | Demonstrate control of production /service provision e.g. appropriate measuring/monitoring activities, adequately resourced, supported by documented information, to show you can achieve planned results. <i>Also ensure people are competent to do their jobs.</i> | | | | | | |
| | Adequate controls for handling property belonging to customers and external providers so it is identified, verified, safeguarded. | | | | | | |
| | Ensure requirements for post-delivery activities are met e.g. dealing with undesired consequences, warranties, maintenance, disposal. | | | | | | |
| 8.6 | Products/services are only released to customers once conformity has been confirmed. <i>This is a layer of quality control.</i> | | | | | | |
| 8.7 | Outputs that do not conform should be identified and controlled to prevent unintended use. Appropriate action should be taken in these cases e.g. segregation, correction, inform customer, acceptance of non-conforming product/service by the customer (which must be documented). | | | | | | |

Clause 9 - Performance Evaluation

The organisation is required to determine what needs to be monitored, how to monitor and when to do it.

| Clause | Plain English Description | Yes | No | Gap Identified/Corrective Action Required | Owner | Target Date | Date Completed |
|--------|---|-----|----|---|-------|-------------|----------------|
| 9.1 | Determined what needs to be monitored and measured and when. | | | | | | |
| | Established methods for monitoring, measuring, analysing, evaluating and when this should be done. | | | | | | |
| | Customer satisfaction is measured with appropriate techniques. <i>For example, surveys, feedback forms, meetings.</i> | | | | | | |
| | The above is used to evaluate conformity and effectiveness of processes and identify need for improvements in the QMS. | | | | | | |
| 9.2 | Established a planned, programmed approach to internal audits. | | | | | | |
| | Results of internal audits are reported to management, appropriate corrective action taken. <i>You may wish to attend an Internal Auditor training course to learn how to do this.</i> | | | | | | |
| 9.3 | Management review meetings are taking place as planned and documented evidence is available. | | | | | | |
| | There is an appropriate agenda for the management review meetings to cover all requirements as stated in 9.3.2 of the standard. | | | | | | |
| | There is documented evidence of the outputs of the reviews, identifying opportunities for improvement, any required changes to the QMS and how to resource any changes required. | | | | | | |

Clause 10 - Performance Evaluation

Underpinning the concept of a QMS are the principles of corrective action and continual improvement. The organisation must identify opportunities for improvement as well as introduce necessary actions to meet customer demands and increase customer satisfaction.

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|--------|---|-----|----|---|-------|-------------|----------------|
| 10.1 | Have a system for, and be able to provide examples of, identifying and implementing opportunities for improvement. | | | | | | |
| 10.2 | Have a process for reacting to nonconformities, correcting them and dealing with consequences. | | | | | | |
| | Review and analyse nonconformities, determining the cause and take corrective action. <i>To ensure mistakes and errors are not repeated.</i> | | | | | | |
| 10.3 | Overall, an approach to continually improve the suitability and effectiveness of the QMS. <i>Much of this will be covered in clause 9.</i> | | | | | | |

About Global Standards

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At Global Standards Co., we strive to be a catalyst for success in the business consulting industry. Through our integrated solutions, we provide our clients with the tools they need to work effectively and efficiently – helping them achieve their goals with timely precision.

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