



ISO 9001 : 2015

What can you expect from the certification process?

Quality Management System Checklist

This checklist will provide you with a detailed understanding of what you can expect to have in place, and be doing, by the time you complete the ISO 9001 certification process. If you don't have any of this in place already, don't panic; QMS are happy to provide you with the necessary templates and guidance, during the QMS 3-stage certification process, until you do.

Context Of The Organisation

This means: understanding external and internal issues, as well as the needs and expectations of interested parties, and where you sit in all of this.

- We have thought about and set out the external and internal issues that are relevant to our organisation's vision, purpose and strategic direction.
- We've set out a way of reviewing and checking these as well as timescales for doing so.
- We understand which parties have an impact on the ISO 9001: 2015 Quality Management System, and the needs and expectations that they have.
- Our Quality Management System addresses the external and internal issues, the needs and expectations of all parties, as well as our strategic vision, objectives, products and services.
- We've carefully set out the processes, actions and requirements at each stage within our Quality Management System.
- We've also set out how each of these stages will be managed, who is responsible, how they need to action things and how success will be measured.
- We understand how to adjust our Quality Management System as the context of our organisation changes.

Leadership

This means: the role your top management will play in leading, not just managing, your Quality Management System and actions required during the certification process.

- Our top management have understood the certification process and have taken responsibility for the effectiveness of our Quality Management System.
- Our Quality Management System is structured to reflect the strategic vision and priorities of our organisation. This has been communicated throughout the organisation so that everyone understands how it is relevant to overall success.

- We have a framework for communicating our objectives clearly at all levels of the organisation – strategic, functional, departmental and individual.
- We are able to integrate the policies and procedures set out in the Quality Management System into our day-to-day way of working.
- Our managers understand the importance of communicating the processes set out in the Quality Management System and the role that risk-based thinking will play in our success.
- Throughout our organisation; customer, statutory and regulatory requirements are considered, set out, met and communicated.
- We've considered all of the possibilities that can affect whether our products and services deliver positive customer satisfaction.
- We've considered both the risks and opportunities that exist within our own processes, taking the appropriate steps to act on these findings.
- We have clearly set out who is responsible for making each part of the Quality Management System a success, as well as who is responsible for making decisions.

Planning

This means: evaluating success, measuring risks and opportunities and planning the steps needed to increase desirable effects, prevent unwanted effects and achieve improvements.

- We have a framework for identifying the risks and opportunities that affect our processes and the Quality Management System.
- We have planned what we need to do to meet our quality objectives
- We have integrated the steps that need to be taken into our day-to-day practices and systems and not just treated them as 'one-off' tasks.
- We've thought about the ways in which we might need to change the Quality Management System, over time, to ensure it stays effective.

Support

This means: making sure you have the resources and tools you need to run and continually improve your Quality Management System.

- We understand what resources (people, infrastructure, working environment etc.) we need in order to establish, implement and maintain our Quality Management System.
- We have also set out a plan for reviewing resources on a regular basis, to make sure we continue to provide sufficiently trained staff and the right equipment and materials to meet our customer's expectations.
- We recognise that accurately measuring and monitoring the ways in which our products and services meet quality criteria and conformity requirements is important. So we have identified the resources required to provide valid, reliable results.
- We have made sure that we have a good infrastructure in place to ensure that conformance to the Management System Standard and legal compliance is met, both now and in the future.
- We recognise the levels of understanding we must have, to ensure that our processes can work effectively, and our products/services conform to the expected criteria set out in our Quality Management System.
- We have taken steps to ensure that the people impacting on our Quality Management System are appropriately trained or that training needs have been identified to help them achieve the required qualifications.
- We've made sure that each person in our organisation understands how they can contribute to making this Quality Management System a success.
- We've planned internal and external communications to make sure everyone knows about the Quality Management System.
- We understand what documented information needs to be provided – both to satisfy the requirements of the Standard and to ensure the requirements continue to be implemented effectively.

Operation

This means: the steps you need to take to get going on your Quality Management System.

- We have clearly set out processes to ensure we produce products and deliver services that meet the requirements specified by the Standard.
- Any changes that need to take place will be considered carefully, within the structure of our Quality Management System, and carried out in a way that will ensure continuing relevance and success.
- We have a clearly defined process for communicating with customers (and gaining their feedback) in relation to all products, services, enquiries, contracts and order handling.
- We start this communication process, with customers, before they actually 'contract' with us, so as to better understand their expectations.
- We make sure all the processes, products and services we provide meet the requirements of the Standard.
- We are committed to selecting, monitoring and evaluating external providers, using a clearly defined process.

- We make sure that, when providing products and services, documentation is made available which sets out the characteristics and what we plan to achieve, and is made available to others.
- Activities are monitored and measured, at appropriate stages, to ensure that agreed standards for processes, outputs and acceptance have been met and all people involved in the process have been proven to be competent.
- We ensure the identification and traceability of whatever we produce/provide.
- We make sure that any property belonging to customers or external providers, used during the provision of products or services, is controlled effectively.
- We understand the importance of post-delivery activities and have set out clear steps for ensuring that these (e.g. warranty, maintenance, recycling, disposal etc) are understood and managed.
- Should anything produced not conform to the standard expected, then we will manage this to make sure that it is not used or delivered.

Performance Evaluation

This means: using your experience and knowledge to monitor, measure and analyse processes and changes, to consistently seek out ways to improve quality.

- We understand what we need to monitor and measure and have set out the ways in which we will do this, to get useful, valid results.
- We have agreed when we need to analyse and evaluate these results
- We have set out the ways in which we will monitor customer perceptions and the ways in which their needs and expectations have been met.
- We have agreed a formal structure for evaluating our Quality Management System, through an internal audit programme.
- We will agree any areas for potential improvement and development, within the Quality Management System, and how we will include these in management reviews.
- We have set out a structure for management reviews and are committed to implementing it, to regularly monitor and evaluate the implementation of our Quality Management System.

Improvement

This means: using the results from your evaluation and analysis to identify ways to enhance the Quality Management System that serve to increase customer satisfaction.

- We have identified areas for improvement that focus on meeting customer requirements and enhancing their satisfaction. We have also taken the steps necessary to put these changes into action.
- We have a process for managing the ways in which we do not conform to the Standard, and the steps we need to take to correct this.
- We have agreed how we will prioritise the continual improvement of the suitability, adequacy and effectiveness of our Quality Management System.