



ISO PDF FREE DOWNLOAD

Our Essential Guide To:

ISO 9001:2015

Quality Management Systems



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Essential Guide To: **ISO 9001:2015**

What is ISO 9001:2015?

A management standard that:

- Improves the consistency of your products and services
- Enables access to tendering processes hence larger customers and bigger opportunities
- Encourages measurable company growth
- Acts as a differentiator in the market
- Adds credibility and status to your company



Does it work? What do certified businesses say?

- Customer satisfaction and loyalty levels improve
- Operational efficiency increases
- New business is won
- More existing customers are retained
- Cost savings are made

What are the ISO 9001:2015 Quality Management System (QMS) requirements?

Put simply, to provide appropriate records to show that you manage the business with a focus on meeting customers needs and ensuring the business operates as you intended. Heavily documented procedures are no longer necessary, though most businesses find having some written instructions is useful.

What Are the Key Areas of Focus? (Continued on next page)

The standard is broken down into sections ("clauses") which define the extent and boundaries of the management system. This means that the QMS is built around the vital core areas of the enterprise, not peripheral ones.

"The Context of The Organisation"

Simply, as a company:

“What are our aims?”

“What our Key Products and Services?”

“Who are our customers and other affected parties (summarised)?”



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Leadership

Defined and agreed roles and responsibilities for senior management are vital in a successful organisation. This clause ensures that someone takes ownership of the QMS from a supervisory position at a senior level. It involves a shared “Quality Policy Statement”.

Planning

Having defined what your company actually does, and to whom, and what the risks and opportunities are, this clause assesses the impact of risks, and how to control them. Next, it considers setting quality objectives, as well as detailed plans of how these will be achieved, who is responsible, and what time scales are involved. Finally, but crucially, it sets definite guidelines for managing changes.

Support

Simply, how can the resources required to complete tasks be controlled and measured, and how do you know the method of measurement is known to be accurate?

Who are the key people with mission-critical knowledge about your organisation? What are the general levels of competence and awareness across the business for what needs to be achieved? How are vital documents controlled?

Operation

The largest section, focussed on “doing”! It covers the documentation of requirements for each of the organization’s specific products or services, and the processes needed to produce or create them.

Put bluntly:

“How do we know when something is fit for purpose and will meet customer’s needs, and how do we make sure this consistently happens?”

...and...

“What are the resources required to achieve this? How do we measure if it's actually happening?”

This clause addresses design and development, external providers, production and service provision, release of products and services, nonconforming outputs (things going wrong). From work on this clause, a QMS (quality management system can be created)

Performance Evaluation

How do you know if the quality management system is delivering what you intended? Who checks it, and how? How do you know if customer’s are satisfied? How are internal audits conducted, and what is the input of senior management to the QMS and whole process?

Improvement

How do we improve, and stop things going wrong? How do we implement corrective actions when necessary, and continually improve your quality management system, keeping records as required?



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What are the Steps to ISO 9001:2015 Certification?

Understand what it is! Many companies think it's simply a certificate on a boardroom wall gained by an auditor visiting for a day and checking things. Others think that means a set documented procedure for everything from opening letters, making coffee to checking products. Neither is true. Certification means that an effective quality management system has been designed to serve your organisation's aims and help you do better business

Prepare your organization. Educate on the above, clear misconceptions. Broadly define the "why", "what" and "how".

Most importantly, gain commitment from senior management. The project needs to be driven by key influencers in the organisation, beyond the initial decision to proceed and through to successful and effective implementation. The key success factor is integration, that is, of weaving the management system into the daily reality of business life. Failure to impact organisational behaviour comes when ISO 9001:2015 is seen as a bolt-on, nice-to-have, side-show to the main activities of the enterprise. Only sound commitment from senior management at every stage can ensure success.

Gap Analysis

Having defined what your company actually does, and to whom, and what the risks and opportunities are, this clause assesses the impact of risks, and how to control them. Next, it considers setting quality objectives, as well as detailed plans of how these will be achieved, who is responsible, and what time scales are involved. Finally, but crucially, it sets definite guidelines for managing changes.

Project Plan. Set some goals and timescales!

Here are some areas to consider:

- When will you start your QMS implementation project?
- When do you want/need to complete implementation?
- What gaps exist in your existing QMS and how long will they take to address?
- What resources are available or lacking?

Training

Training equals awareness, promotes ownership, encourages participation, and means success!

Potential parties to train:

- Project Manager(s)
- Team Leaders
- All significant employees, teams and internal auditors



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Documentation

Create your QMS. What are your business processes, and how do they interrelate? For example, list the departments affected, and design a flow chart of interaction between them. What are the processes, and how are they measured? Off-the-shelf documentation is available as a template. A document control system is vital to make sure everybody gets the right documentation, and any updates, and should be implemented at an early stage.

Use and Improve QMS Start using your QMS ahead of a certification audit! Fine-tune or redesign as required. Conduct internal audits, management review meetings, and keep records.

Internal Audits

A test-run before The Big Day of the external audit. An impartial third-party (such as your friendly ISO Consultant) should look for conformity, effectiveness, and potential non-compliance. You could even train up your own team of internal auditors. We can help with that, too.

ISO Registration

After running your QMS for 2-3 months, it's time to arrange an external audit from a certification body. Again, your ISO Consultant should be able to assist with this.

What is the cost of ISO 9001 certification? How prepared are you? This determines the number of external consultant's days required. Alternatively, if you have sufficient in-house expertise, then a "certification toolkit" may work for you. We offer several options, with varying levels of help desk remote support.

The Next Stage? If you've read this far, well done! We pride ourselves in our straightforward, practical and (occasionally) painfully honest approach. We want to make simple what others tend to make complex. If it sounds like we could work together, please get in touch!



We can help you achieve certification in any one of three ways:

