Information Guide

PQSmitra
Simple & Practical

ISO 9001:2015 Quality Management System (QMS)

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What is ISO 9001?

ISO 9001 Quality Management System (QMS) is an internationally recognized standard, which can be applied / implemented to any production or services industries. This standard can be uniformly applied to organizations of any size or description. It was drawn up by the International Organization for Standardization (ISO), with intent to set international requirements for Quality Management System.

The focus of ISO 9001 QMS is to streamline the business processes for the better performance and sustainability of the business. ISO 9001 Standard is utilized to standardize the processes in all the industries by organizations to exhibit their capacity to consistently provide products and services that meet client and regulatory prerequisites and to show continuous improvement, it does not characterize an item's quality.

The 2015 version is a 10 clause structure and has adopted P-D-C-A cycle, risk-based thinking and requirement to determine context of the organization. Besides this, the new version of the standard excludes requirements for preventive actions, quality manual and management representative.

What are the Focus Points of ISO 9001:2015 Implementation?

- Streamlining and Standardizing the business processes
- Formulating Quality Policy and Objectives
- Setting up system for documentation and records.
- Management information system
- Risk management for the business
- Business performance and sustainability

What are the documents required for ISO 9001 certification?

The organization shall demonstrate continual improvement in the field of quality management system by maintaining, establishing, implementing and providing documented information.

The documented information required for ISO registration

- The organizations scope
- The organizations Quality policy and Quality Objectives
- A Quality Manual
- Standard operating Procedures
- Records at individual process / department. E.g. Sales, Purchase, Production, Quality Assurance, Maintenance, Customer Service.

Who all are eligible for ISO 9001 Certification?

- Manufacturing units
- Service sector including Educational institutes, Hospitals and other service providing units
- Trading units
- Any other business units irrespective of nature of business, size and location.

How will ISO 9001 Certification benefit your Organization?

- Business process streamlining and efficiency improvement
- Satisfaction and Retention of Valuable Customers
- Responsibility and Accountability across the organization
- Elimination of non-value-added activities from the system
- Good Marketing Tool and Credibility in Overseas Business.
- Better sustainability prospects

How did ISO 9000 evolve throughout the year?

Year 1987 – Publication of ISO 9000 series if standards

Year 1994 – 1st Revision of the standard (20 clauses and 20 required procedures)

Year 2000 – 2nd Revision of the standard (8 clauses and Process approach introduced)

Year 2008 – 3rd Revision of the standard (Minor revision for clarification of words)

Year 2015 – 4th Revision of the standard (10 Clauses and Risk assessment included)

What are the Reference Standards for ISO 9001:2015

- ISO 9000:2015 - Quality management - customer satisfaction - Guidelines for complaint handling in organizations
- ISO 9004:2018 - Quality management - Quality of an organization -- Guidance to achieve sustained success
- ISO 10002:2018 - Quality management - customer satisfaction - Guidelines for complaint handling in organizations
- ISO 19011 - guidelines for auditing management systems

What is the validity of the QMS ISO 9001 Certification?

- The validity of the ISO 9001 Certification is 3 Years with a surveillance audit after every 1 year.

How long will it take me to get ISO Certified?

- This dependence on a number of factors, like the size of your firm, the complexity of your processes, the procedures you already have in place, and so on. Implementation can take 2-3 months for a smaller company (less than 100 people) and 5- 6months for a larger organization (more than 100 employees). The procedure is also influenced by the amount of time and resources your firm has to devote to implementation. That time should be factored into your overall schedule ahead of time, especially if you have a registration deadline to meet

What is the difference between ISO 9001, ISO 9002 & ISO 9003?

In ISO 9000 version 1987 and 1994 there were 3 standards namely; ISO 9001, ISO 9002, ISO 9003. ISO 9001 was applicable for all organization involved in design, manufacture and supplier of products.

ISO 9002 was applicable for organization involved in manufacture and supply.

ISO 9003 was applicable for organization involved in offering services.

Later on in the revision of 9001 standards was revised in 2001

These 3 different standards were combined and named as ISO 9001 as a generic standard coming from various organizations irrespective of the activities performed by the organization. At present only 9001 standards are in existence and activities performed by the organization are mentioned in the scope appearing on the individual certificate rewarded.

What happens to my existing Certificate when any standard is revised?

Generally, whenever there is a revision, the previous standard is kept valid for 2 to 3 years. It is also called as transition period. Earlier the organization certified as per previous standards is expected to upgrade and get certified in accordance with revised new standard.

Does QMS ISO 9001 standards get combined with other standards?

Because ISO 9001 is a sector-neutral standard, it is appropriate for certification of all organizations quality management systems Audits conducted in accordance with ISO 9001. For quality management, it can be supplemented with other industry-specific audits systems, as well as other types of management software.

How much does QMS ISO Certification Cost?

The ISO certification cost is determined by a variety of criteria, including internal resourcing capabilities, pre-existing management system documentation, as well as the size and scope of products and services offered by the organization. The cost of the Certification Body and the cost of the ISO Consultant are two of the most important charges involved.

After initial QMS ISO Audit, what is the time frame for receiving the Certification?

It takes 15 to 20 days after the 2nd stage of the ISO Audit.

Is QMS ISO 9001 Certification (ISO Registration) difficult?

An ISO certification will need time, effort, and improvement from a variety of departments inside a company. The steps that must be done, however, are well worth it for any organization. Owners, staff, and customers will all gain from it.

How to check the validity of the QMS ISO Certification?

To identify the authenticity of your accreditation body, one must

Visit the IAF - International Accreditation Forum website home page

Go to the IAF - International Accreditation Forum MLA–Multilateral Recognition Arrangement signatory's category

Select the recognized AB – Accreditation Body sub category or recognized region sub category

From there you will select your country or the country your accreditation body belongs to

After which you can visit the website and look for your certification body.

How will PQSmitra help you with Hassle Free Implementation process for QMS ISO 9001 Certification?

PQSmitra adopts a result oriented approach for the effective system implementation at the organization. This simple and practical method of system implementation helps organizations to enhance the business performance and sustainability. PQSmitra offers 100% documentation support to achieve successful certification in addition to enhanced business performance. The implementation process is described below:

- Initial visits and review of the existing system
- Gap analysis and planning for the documentation (Records and Procedures)
- Identifying an Accreditation Board of your choice (UKAS, NABCB, JAS-ANZ,DAKKS, ANAB, SINCERT)
- Training and Hand holding/ support for implementation
- Select a Certification Body (TUV, Bureau Veritas, Intertek, DNV, SGS India, DAS Certification, BSCIC.
- Submission of updated questioner to Certification Body
- Finalization of Commercial terms
- Internal audit for verification of implemented system
- Management review
- Certification audit – Stage 1
- Certification audit – Stage 2
- Closure of non-conformities
- Rewarding the certificate to the organization
- Performing the Surveillance audit at frequency of 1 year

PQSmitraService Features appreciated by clients

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