Qualio

How to prepare for ISO 9001 certification

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Getting your ISO 9001 certification

Earning your ISO 9001 certification isn't as complicated as you might think. Your life sciences company isn't mandated to seek ISO certification, but choosing to do so can benefit your organization in the following ways:

1. It lowers your costs across all aspects of your business. It instills a specific way of doing things that keeps you from needing to re-tool or start over
2. It gives you access to a broader worldwide market because some customers will only purchase from companies that are ISO 9001 certified
3. It provides a framework for quality management processes, which improves consistency and efficiency
4. Gives your customers the confidence that your product is safe and does what you say it will
5. Certification encourages continuous improvement and innovation

Earning an ISO certification demonstrates that an ISO auditor has performed an audit of your company and found that you comply with their guidelines.

Many life science organizations choose to get certified to ISO 9001 as a foundational stepping stone to niche industry standards (like ISO 13485) or to simplify the embedding of day-to-day QMS processes like GxP.

This guide focuses on the key steps you and your business should take to prepare for your ISO 9001 journey.

What is ISO 9001 certification?

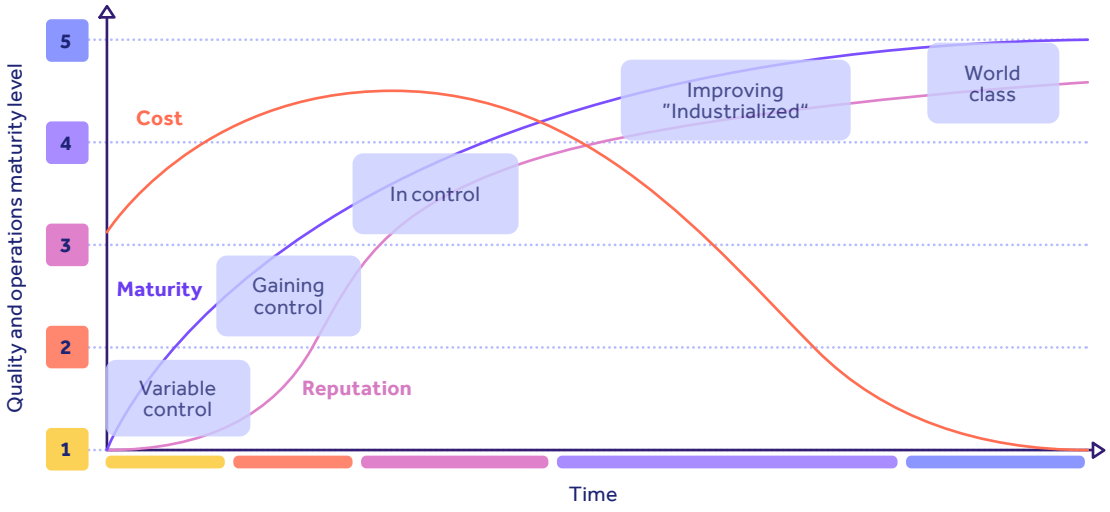
> *ISO is an independent, non-governmental, international organization with a membership of 164 national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market-relevant International Standards that support innovation and provide solutions to global challenges.*
>
> **— ISO (International Organization for Standardization)**

ISO 9001 is a certification you can acquire by following specific standards and guidelines for a quality management system with a strong customer-centric focus.

Becoming ISO 9001-certified ensures your customers receive top quality products and services consistently, and allows your organization to begin its journey up the maturity curve to a world class QMS.

The journey to world class

Quality maturity curve



11 benefits of ISO 9001:2015 accreditation

01. Bringing quality and continuous improvement into the heart of your organization

02. Aligned business

03. Leadership commitment

04. Opportunity *and* risk management

05. An integrated approach through Annex SL

06. Profitability

07. Governance tool

08. Adapt to a changing world

09. Greater customer focus

10. Consistent foundation for the future

11. Meet the needs of all interested parties

Key components of ISO 9001 compliance

General

Adoption of a quality management system to:

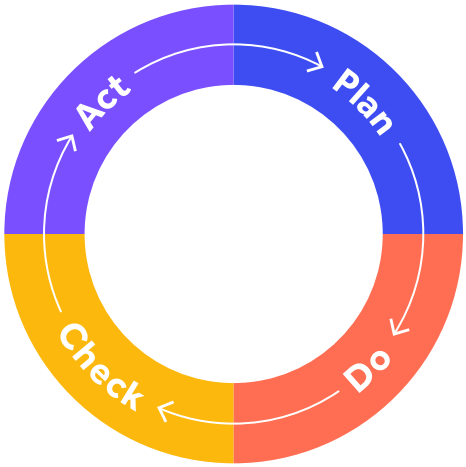
1. Consistently provide products and services that meet customer needs and applicable statutory and regulatory requirements
2. Demonstrate conformity to specified QMS requirements
3. Address opportunities to enhance customer satisfaction
4. Address both risks and opportunities associated with your context, objectives and strategic direction

Quality management principles

1. Customer focus
2. Leadership
3. Engagement of people
4. Process approach
5. Improvement
6. Evidence-based decision making
7. Relationship management

Process approach

Employs the process approach: incorporating the Plan-Do-Check-Act cycle and risk-based thinking.



Relationship with other management system standards

1. Annex SL: for consistency
2. Other ISO standards: for better integration

Clause-by-clause breakdown

1. Scope

The scope sets out the intended outcomes of your management system. The outcomes are industry-specific and should be aligned with the context of your organization (Clause 4).

- Demonstrate ability to consistently supply products and services that meet customer and applicable statutory and regulatory requirements.
- "Output resulting from product realization" has been removed from ISO 9001:2008 to reflect changes to the definition of process and output.

2. Normative References

Provides details of the reference standards or publications relevant to the particular standard.

3. Terms & Definitions

Details terms and definitions applicable to the specific standard in addition to any formal related terms and definitions standard.

Main changes from ISO 9001:2008:

- Risk
- Innovation
- Management responsibility › Leadership
- Purchasing and outsourcing › Externally provided processes, products and services

4. Context

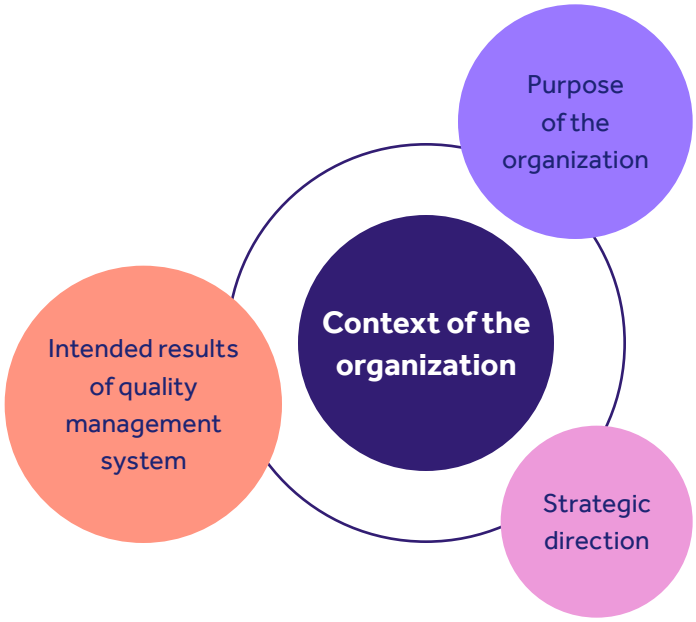
The context of the QMS and how your business strategy supports this. Clause 4 determines why your organization is here.

A. Understanding the organization and its context (**new requirement!**)

B. Understanding the needs and expectations of interested parties (**new requirement!**)

C. Determining the scope of the management system

D. The management system



5. Leadership

Concerns the role of "top management": the group of people who direct and control your organization at the highest level.

A. Leadership and commitment (**new requirement!**)

B. Policy

C. Organizational roles, responsibilities, and authorities: Enhanced requirement

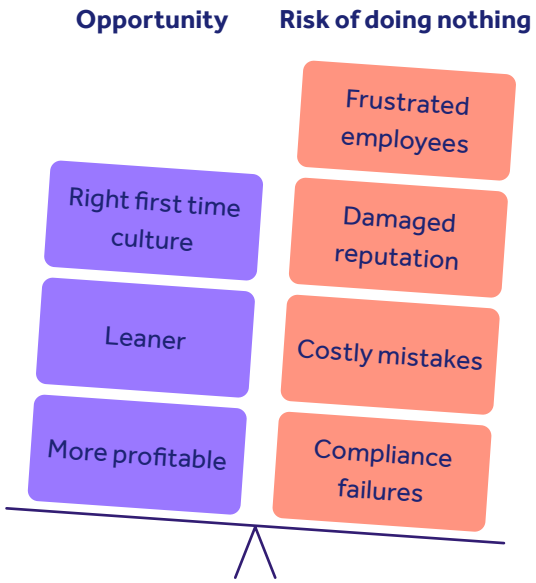
6. Planning

How your organization plans actions to address both risks and opportunities.

A. Actions to address risks and opportunities

B. Management system objectives and planning to achieve them

C. Planning of change



7. Support

Get the right resource to the right people and the right infrastructure in place

A. Resources
B. Competence
C. Awareness
D. Communication
E. Documented information

8. Operation

How to meet customer requirements and execute plans and processes. Consider risks associated with a product or service, customer requirements, customer feedback, and any statutory requirements.

A. Operational planning and control
B. Requirements for products and services
C. Design and development of products and services
D. Control of externally provided processes, products and services
E. Production and service provision
F. Release of products and services
G. Control of non-conforming output

9. Performance evaluation

Measure and evaluate your QMS to ensure that it is effective and to determine what, how and when things are to be monitored, measured, analyzed and evaluated.

A. Monitoring, measurement, analysis and evaluation
B. Internal audit
C. Management review

10. Improvement

Determine and identify opportunities for continual improvement of the QMS

A. Non-conformity and corrective action
B. Continual improvement

The process approach

- First appeared in ISO 9001:2000
- Anecdotal evidence suggests it is poorly understood
- ISO 9001:2015 places increased emphasis on the process approach
- Although it is not explicitly mandated, the requirements set out in sub-clause 4.4 – 'the QMS and its processes' - drive you down this route.

In 2008, TC 176 produced 'Guidance on the concept and use of the process approach for management systems'. This now needs a refresh, but its implementation phases are essentially unchanged.

Start by systematically defining your core quality management system processes and their interrelationships (this can take time if your organization is particularly large or complex).

Then use P-D-C-A to manage and improve your processes, and risk-based thinking to avoid unintended process outcomes.

The process approach introduces horizontal management, controlling processes which flow across departmental boundaries and ensuring someone is accountable for the process from start to finish.

The whole picture, from process initiation to process completion, should be visible and traceable. Stakeholder desires should be mapped onto each step of the process, with delegated authority to realize them.

Employee loyalty should be to their assigned projects, products or services, not their own departments.

8 top tips for preparing for an ISO 9001 process approach

01. Involve staff in building the process-based QMS, including the initial definition of processes and subsequent P-D-C-A steps

02. Train individuals so they understand their roles and accountabilities in respect of the core processes

03. Ensure staff see their processes end-to-end

04. Restructure the audit program around processes, not functions

05. Train auditors to follow processes across departments, paying particular attention to interdependencies and interactions

06. Provide documented information to support the operation of processes

07. Test your processes are effective

08. Rebrand your processes

Which processes should I include?

That's up to you. ISO 9001 doesn't mandate it for you. Focus on your core processes, the ones which keep you awake at night, and ask yourself which play a significant role in ensuring:

- You are constantly providing products and services which meet customer, statutory and regulatory requirements
- You are enhancing customer satisfaction

Ensure you are controlling these. Processes for claiming expenses or booking meeting rooms should not be on your list!

Examples:

1. Change management
2. Risk management
3. Incident management
4. Documentation
5. Compliance
6. Governance
7. Feedback
8. New supplier
9. Equipment management
10. Customer onboarding
11. Audit
12. Data retention
13. Competence management

7 steps to prepare for ISO 9001 certification

Preparing for ISO 9001 certification doesn't have to be complicated. Follow these seven steps to help you get your company ready for an ISO 9001 audit.

1. Familiarize yourself with the guidelines

Before you do anything else, you need to read the ISO 9001 guidelines and make sure you understand what's required of you to earn your certification.

You can find the ISO 9001:2016(en) document on the iso.org website. Click here to see a preview and purchase the paper from their website now.

2. Have a customer-centric focus

When developing your standard operating procedures (SOPs), you need to plan for your customers' current and future needs, the requirements your product needs to fulfill for them, and how you're going to gather their feedback.

Feedback from your customers is vital for making adjustments to improve the quality of your product. Your success hinges on their continued satisfaction and use of your product.

3. Develop and train your leaders

Your leaders are the foundation for the success of your company. A great leader strives to build trust between themselves and their team.

They set goals, motivate their team, and recognize achievements and hard work.

Giving your leaders the training and tools they need to succeed ensures your ability to create top-quality products for your customer's patients consistently.

4. Develop and train your team

Training and developing your team is every bit as important as training your leaders. Have clear and complete procedural information readily available, require training, and provide your team with all necessary educational materials they need to complete their training.

Your company culture should encourage them to ask questions and to seek clarification when necessary. Your team should be comfortable sharing their concerns so you can always be improving.

5. Measure and track critical data

Measuring and tracking data is a crucial part of successfully achieving ISO 9001 certification. Without evidence, you can't make informed decisions or take corrective action in underperforming areas, which could result in denial of your certification request.

6. Define and refine your processes

Manufacturing processes are the specific set of standardized tasks used by people or equipment to produce a product or service for particular customers. Business processes are a collection of related activities structured in a specific sequence to get important things accomplished.

The more streamlined and organized your processes are, the better your outcome. This will make things more efficient and reliable, which results in higher-quality products with fewer safety hazards or mistakes.

7. Implement an eQMS

Paper-based quality management systems have some serious disadvantages.

Searching through file cabinets or scattered papers on your desk is inefficient, has quickly become outdated and could be considered careless upon review.

Accidents happen, and you don't want essential documents to be accidentally ruined by spilled coffee or tossed out because they were mistaken as trash.

A secure cloud-based eQMS consolidates all your critical documents and communications in an electronic format that allows you to quickly and easily find the right information at the right time.

An eQMS like Qualio incorporates ISO guidelines so you can follow best practices and maintain ISO compliance without relying on employee's brains, paper notes, and overflowing file cabinets to keep track of crucial information.

Before choosing a software provider, think carefully about your needs and select an eQMS that is simple to use, reliable, scalable, and is ISO 9001- and ISO 13485-compliant.

An eQMS built for life sciences companies provides many benefits you would otherwise miss out on by relying on paper-based methods or using inadequate software.

With the right eQMS, you can get your products into the hands of your customer's patients quickly, as well as:

- Lower costs, speed up automation, and reduce the need to re-tool or develop and tweak processes
- Make data-backed decisions vs. relying on gut feelings by tracking and recording data
- Inspire and motivate your team because your eQMS encourages continuous innovation and allows you to repeat best practices throughout your organization

And much more.

ISO 9001 vs. ISO 13485

ISO 9001 lays the framework for a quality management system that can be applied no matter what industry you're in or what your product, service, or company size is.

If your company intends to manufacture medical devices, you'll need to seek ISO 13485 certification. ISO 13485 has additional requirements not found in ISO 9001 that are specific to medical device manufacturers.

Let's take a look at the similarities and differences between ISO 9001 and ISO 13485, so you can get a better understanding of where you need to raise the bar on quality as a medical device manufacturer.

Similarities between ISO 13485 and ISO 9001

- Each standard helps organizations achieve a quality management system
- Both place a focus on risk mitigation and assessment
- Both utilize the Deming cycle, also known as Plan Do Check Act
- They each place a focus on competency and infrastructure for quality
- Both emphasize understanding the customer for the realization of quality products

Additional requirements for ISO 13485

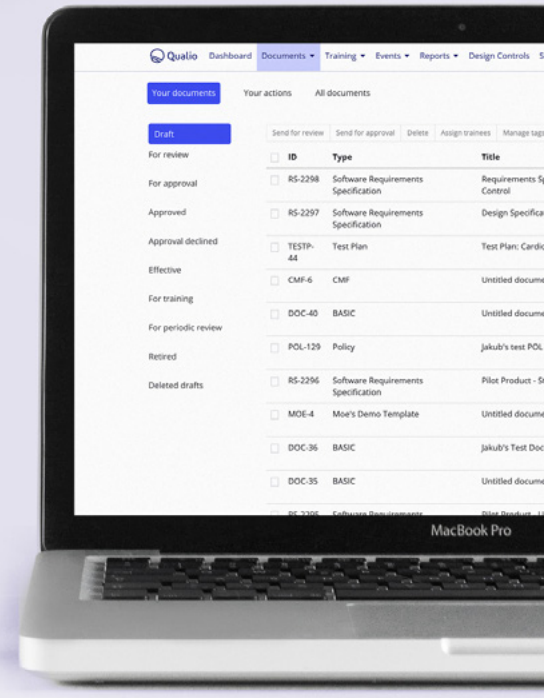
- Device master record explicitly defining QMS requirements
- Feedback and review system for non-conformance detection
- Product quality control (monitoring and measuring) throughout production process
- Set quality requirements must be met before product release and delivery
- Advisory notices, rework activity, release of non-conforming product (which still meets regulatory requirements) must be documented

- Personnel require access to procedures, requirements and reference materials at the point of work
- Unique and specific records for every approved and verified device batch
- Installation and verification device requirements
- Maintained records of device installation, verification and servicing activities and procedures
- QMS containing product specification documents and quality policy, with a framework for reviews and updates controlled by the management team
- Management must verify QMS goals and compliance
- Documented procedures for shelf life, quality data collection/analysis/retention, maintenance activity, risk/environment management, adverse event flagging, product conformity, identification, returns, maintenance, labeling and packaging

Get started with Qualio

To make sure you're going to love Qualio before you pull out your wallet, take it for a test drive by scheduling your free demo.

Schedule a demo with us



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