

Guide on ISO 9001:2015

ISO 9001 is the world's best-known quality management standard for companies and organizations of any size. ISO 9001 provides a quality management framework that can apply to organizations of any size or sector. It's a powerful tool that helps manage your business effectively, boost operational resilience and build for the long term.

Through the process of continuing to review and improve systems, the standard can positively help your business to ensure a high level of customer satisfaction and increase the effectiveness of your operations. This will in turn provide opportunities for orders, increased profitability and stability in the business .

Implementing a QMS in organizations of various sizes is not as complex as it is often perceived. Each organization has distinct resources, challenges, constraints, and strengths. It's crucial to remember that the system should be tailored to your organization and its specific processes.

ISO 9001:2015 defines the requirements but does not prescribe how to apply them. Therefore, the first step is to understand the standard and its requirements; the next step is to decide how to adapt each requirement to your organization.

To adapt the ISO 9001:2015 standard to your system, you can start by addressing the following topics within your organization:

- 1. Scope:** The standard aims to create a system that reassures customers of consistent quality, requiring only a simple policy statement and acknowledgment of relevant regulations.
- 2. Normative References:** ISO 9000:2015 is the only mandatory reference document.
- 3. Terms and definitions:** ISO 9001:2015 does not include any terms or definitions. To fully grasp the technical meanings, it's essential to refer to ISO 9000:2015.
- 4. Context of the Organization:** This clause requires you to determine any external and internal issues that have an effect on the operations of your business.
- 5. Leadership:** A major element of the leaders close involvement will be to ensure the effectiveness of the QMS in meeting your business objectives. The impact of leadership in your system will be clearly seen in the development, audits, and reviews of your systems
- 6. Planning:** The intention of this clause is showing the importance of planning, checking and auditing QMS processes.
- 7. Support:** Overall operational demands should be monitored to ensure that the effectiveness is being maintained
- 8. Operation:** Procedures should be detailed and they should be controlled and checked to ensure conformity, and by recording.

9. Performance Evaluation: You will need to thoroughly assess every aspect of the business, including operational performance, customer satisfaction, and supplier performance.

10. Improvement: This clause expresses the importance of improving processes in order to enhance customer satisfaction and remain competitive, to retain and gain contracts by mentioning the key elements of continuous improvement process

6 Planning of the Quality System in ISO 9001:2015

Planning a quality management system requires identifying and addressing risks and opportunities to ensure goals are met, positive outcomes are enhanced, and continuous improvement is supported. Quality objectives must align with the policy, be measurable, and focus on product conformity and customer satisfaction. Changes to the QMS should be carefully planned, considering their purpose, impact, system integrity, and resource allocation.

Main elements of this clause are: Risk and Opportunity Management, Setting and Monitoring Quality Objectives, Change Management, Document Control, Training and Competence Management, Internal Audits and Continuous Improvement, and Supplier Management.

Quality management systems outline process requirements but leave it to the organization to define procedures based on its operations. You may consider the upcoming method to implement Change Management using these elements.

When introducing a new process or modifying an existing one, the organization can use QMS software to manage the change. For example, a pharmaceutical company deciding to implement a new production line can use the software to document the rationale for the change, assess the potential impact on current operations, and assign tasks to relevant team members. The software tracks each step of the process, from approval to implementation, ensuring that no critical steps are missed.

By leveraging these features, QMS software not only makes the process of managing and improving a quality management system more efficient but also enhances the overall effectiveness of the QMS, ensuring that it consistently meets organizational goals and regulatory requirements.