



7 checklists every QMS team needs for their ISO 9001:2015 compliance audit

ISO 9001 is the standard within the ISO 9000 system of standards dealing with QMS requirements. The 2015 revision made it more flexible and easily adaptable to different organizational structures and industries. The changes in the 2015 standard from the 2008 version strengthened the connection between organizations and their quality management system and placed a greater focus on customer satisfaction. As important, it also empowered top QMS leadership to take control in developing and applying quality policies; it effectively made quality everyone's responsibility. ISO 9001:2015 audits evaluate compliance with the standard's seven core principles. Using internal audit checklists helps your team assess your existing quality management processes, identify potential weaknesses, and serve as a reference point before and during a compliance audit.

Here are seven essential checklists your QMS team should have in their toolkit to prepare for an audit.

01

Context of organization

Poor quality management practices in the electronics industry have also directly contributed to waste. Context of organization is new for ISO 9001 and it forces organizations to consider the way internal and external customers and considerations affect their strategic business goals and quality policies.

This checklist helps teams:

- Identify internal and external “interested parties” and develop KPIs to ensure their needs are met
- Showcase leadership’s role in and commitment to quality policies

02

Leadership

This core principle measures executive management’s leadership in implementing QMS and ensuring its success. It requires management to cultivate unity of purpose through communication, defining expectations, and monitoring the organization’s performance.

This checklist helps teams:

- Document leadership’s commitment to customer satisfaction
- Demonstrate how leadership incorporates QMS in the organization’s strategic objectives

03

Planning

Planning as a core principle measures how organizations plan to meet quality objectives, what resources will be required, and who will be responsible for carrying them out. This principle also relates to change planning to ensure changes are carried out in a systematic manner that maintains the integrity of the QMS.

This checklist helps teams:

- Document the cadence and effectiveness of quality planning
- Demonstrate that the organization has the right resources, personnel, and infrastructure in place to meet QMS requirements

04

Support

The support principle focuses on resource management for the quality management system. Specifically, it looks at equipment including hardware and software, communication and information technology, human resources, employee competence and awareness, and document management for all processes.

This checklist helps teams:

- Demonstrate leadership's commitment to people, equipment, and technology
- Document compliance with record keeping and documentation requirements

05

Operation

This principle focuses on operational planning and control over processes needed to develop and produce the organization's products or services. It describes how the QMS is applied to all internal operations and verifies controls are in place to ensure externally provided processes or services conform to specifications.

This checklist helps teams:

- Document that production processes are executed under controlled conditions
- Demonstrate that product identification requirements are met

06

Performance evaluation

The performance evaluation principle deals with the requirements necessary to ensure adequate monitoring of quality objectives. This includes the conformity of products and services, customer satisfaction, and the performance and effectiveness of the QMS..

This checklist helps teams:

- Document critical to quality (CTQ) requirements
- Document control activities that ensure KPIs are being met

07

Improvement

The final section in the core principles covers opportunities for improvement in the QMS and actions that enhance customer satisfaction.

This principle evaluates an organization's systemic approach to improvement across all functional areas and documents evidence of continual improvement.

This checklist helps teams:

- Demonstrate how QMS data helps move the organization forward
- Document quality activities that feed continuous improvement

If you'd like to learn more about QMS requirements, contact Octave today or call: +1 (844) 293-3001

About Octave

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