

# Audit Readiness Checklist For Medical Device Companies

Every medical device company will eventually face an audit, and it's not enough to hope you'll pass. With proper preparation, you can come through it with flying colors. This comprehensive checklist will help you evaluate your organization's readiness, so you can prepare to successfully pass an audit when the time comes.

## Audit Preparation 101

### What is an audit?

Systematic and independent examination to determine whether activities and related results comply with established procedures, standards and regulations and whether these are suitable to achieve objectives.

### Why an audit?

#### Audits are conducted to:

- Determine the effectiveness of the quality system
- Examine the extent of conformity with planned arrangements
- Verify the level of implementation
- Identify opportunities for improvement
- Assure compliance with Standards and applicable regulatory requirements

### Types of Audits

#### First party audit, also known as an internal audit —

Internal audits are conducted for process, product and system.

**Second party audit, an external audit —** An external audit performed on a supplier by a customer or by a contracted organization on behalf of a customer.

**Third party audit, an external audit —** An audit performed by an organization independent of the customer-supplier relationship and is free of any conflict of interest.

## How to ensure readiness through a preparatory audit

- 1 Prepare documents in compliance with the applicable ISO standards and regulatory requirements
- 2 Implement the documents, identify and conduct training
- 3 Conduct a gap assessment of all standard operating procedures (SOPs) and processes
- 4 Develop and implement a comprehensive risk assessment program
- 5 Ensure employees are trained on the applicable regulatory and ISO requirements
- 6 Ensure employees are competent with the applicable regulatory and ISO requirements
- 7 Ensure each employee knows:
  - Where to find the quality policy
  - What the quality policy says
  - Who acts as their management representative
  - Their job description/ responsibilities
  - How they contribute to maintaining the quality of the products or service delivered to the customer
  - Where the SOPs/QMS documents are located
  - Which SOPs are applicable to their job
  - Where their training records are located
  - How to handle nonconforming products/results
  - The quality objectives

# Audit Readiness Checklist

## For Medical Device Companies

Requirement	Key points
<b>Requirement</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Documentation</li> <li><input type="checkbox"/> Regulatory and risk-based approach</li> <li><input type="checkbox"/> Outsourced processes</li> <li><input type="checkbox"/> Change management</li> <li><input type="checkbox"/> Validation of software</li> </ul>
<b>Documentation requirements</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Quality Manual</li> <li><input type="checkbox"/> Medical device file</li> <li><input type="checkbox"/> Controls related to document and record amendment, security and integrity</li> </ul>
<b>Management responsibility</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Focus on regulatory requirements</li> <li><input type="checkbox"/> Documented procedures for management review; documented planned intervals</li> </ul>
<b>Human resources</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Documented processes for competence, awareness and training</li> <li><input type="checkbox"/> Risk based training effectiveness</li> </ul>
<b>Infrastructure</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Processes for preventing product mix-up</li> <li><input type="checkbox"/> Information systems infrastructure</li> <li><input type="checkbox"/> Maintenance intervals for production or monitoring equipment</li> </ul>
<b>Work environment and contamination control</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Documentation requirements for work environment</li> <li><input type="checkbox"/> Contamination controls for sterile medical devices</li> </ul>
<b>Planning of product realization</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Processes for risk management</li> <li><input type="checkbox"/> Requirements for storage, handling, distribution and traceability</li> </ul>
<b>Customer-related processes</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Requirement and availability for any user training;</li> <li><input type="checkbox"/> Documented processes for communicating with stakeholders, including regulatory authorities</li> </ul>
<b>Design and development</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Traceability of design inputs to outputs</li> <li><input type="checkbox"/> Required resources, including competence of personnel involved in design projects</li> <li><input type="checkbox"/> Additional details and documentation for verification and validation plans, including statistical techniques, sampling rationale and representative product and records</li> <li><input type="checkbox"/> Documented procedures for design transfer and design change</li> <li><input type="checkbox"/> Design and development files</li> </ul>

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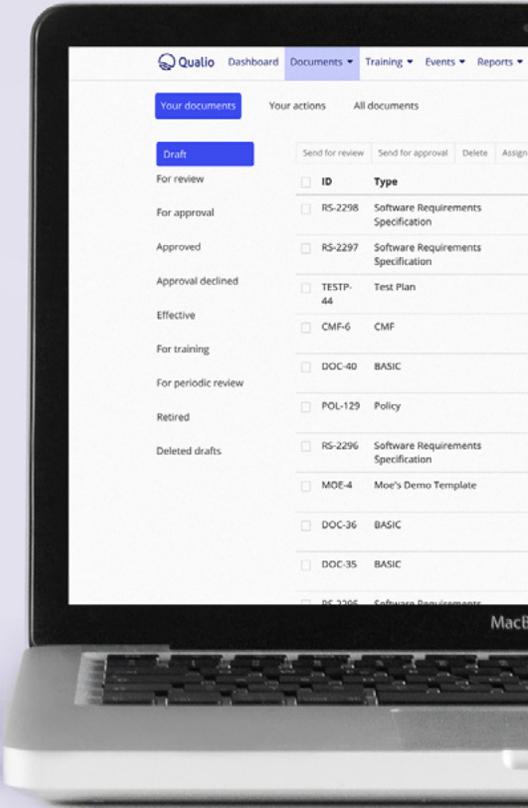
Requirement	Key points
<b>Purchasing</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Increased focus on supplier monitoring and risk</li> <li><input type="checkbox"/> Documented agreements for prior notification of changes to supplied product</li> <li><input type="checkbox"/> Linkage between verification of purchased product and change control</li> </ul>
<b>Production and service provision</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Qualification of infrastructure</li> <li><input type="checkbox"/> Analysis of service records</li> <li><input type="checkbox"/> Documented procedures for validation including statistical techniques, sampling rationale and revalidation</li> <li><input type="checkbox"/> Validation requirements for processes that cannot or are not subsequently monitored</li> <li><input type="checkbox"/> Procedures for risk based software validation</li> <li><input type="checkbox"/> Documented procedure for product identification/status during production; this may be Unique Device Identification (UDI)</li> <li><input type="checkbox"/> Validation of sterile barrier systems</li> <li><input type="checkbox"/> Suitability of packaging systems</li> <li><input type="checkbox"/> Recording of measuring equipment adjustments</li> </ul>
<b>Monitoring and measurement</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Linkages from customer feedback into risk management</li> <li><input type="checkbox"/> Documented processes for ascertaining whether customer requirements have been met</li> <li><input type="checkbox"/> Procedures for complaint handling</li> <li><input type="checkbox"/> Processes for informing third parties of complaints</li> <li><input type="checkbox"/> Plans for internal audits at defined intervals</li> <li><input type="checkbox"/> Processes for the identification of test equipment</li> </ul>
<b>Control of nonconforming product</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Processes for communication with external parties regarding non-conforming product</li> <li><input type="checkbox"/> Controls for managing concessions</li> <li><input type="checkbox"/> Linkages between rework and regulatory requirements</li> </ul>
<b>Analysis of data</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Sources of data for analysis, such as service records and audits</li> <li><input type="checkbox"/> Procedures that cover the application of statistical techniques</li> <li><input type="checkbox"/> Linkages between the analysis and improvement processes</li> </ul>
<b>Improvement</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Actions are taken without undue delay</li> <li><input type="checkbox"/> Evaluation of actions for adverse effects on regulatory requirements and product safety and performance</li> </ul>



# Prepare for and pass your audit with Qualio

Qualio's cloud-based quality management system gives your team the tools to be 100% audit-ready at any time. Learn more about the highest rated eQMS available for medical device companies.

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1.855.203.2010 • +353 1 697 1522