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

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Requirement	Key points
Requirement	☐ Documentation ☐ Regulatory and risk-based approach ☐ Outsourced processes ☐ Change management ☐ Validation of software
Documentation requirements	☐ Quality Manual ☐ Medical device file ☐ Controls related to document and record amendment, security and integrity
Management responsibility	☐ Focus on regulatory requirements ☐ Documented procedures for management review; documented planned intervals
Human resources	☐ Documented processes for competence, awareness and training ☐ Risk based training effectiveness
Infrastructure	☐ Processes for preventing product mix-up ☐ Information systems infrastructure ☐ Maintenance intervals for production or monitoring equipment
Work environment and contamination control	☐ Documentation requirements for work environment ☐ Contamination controls for sterile medical devices
Planning of product realization	☐ Processes for risk management ☐ Requirements for storage, handling, distribution and traceability
Customer-related processes	☐ Requirement and availability for any user training; ☐ Documented processes for communicating with stakeholders, including regulatory authorities
Design and development	☐ Traceability of design inputs to outputs ☐ Required resources, including competence of personnel involved in design projects ☐ Additional details and documentation for verification and validation plans, including statistical techniques, sampling rationale and representative product and records ☐ Documented procedures for design transfer and design change ☐ Design and development files

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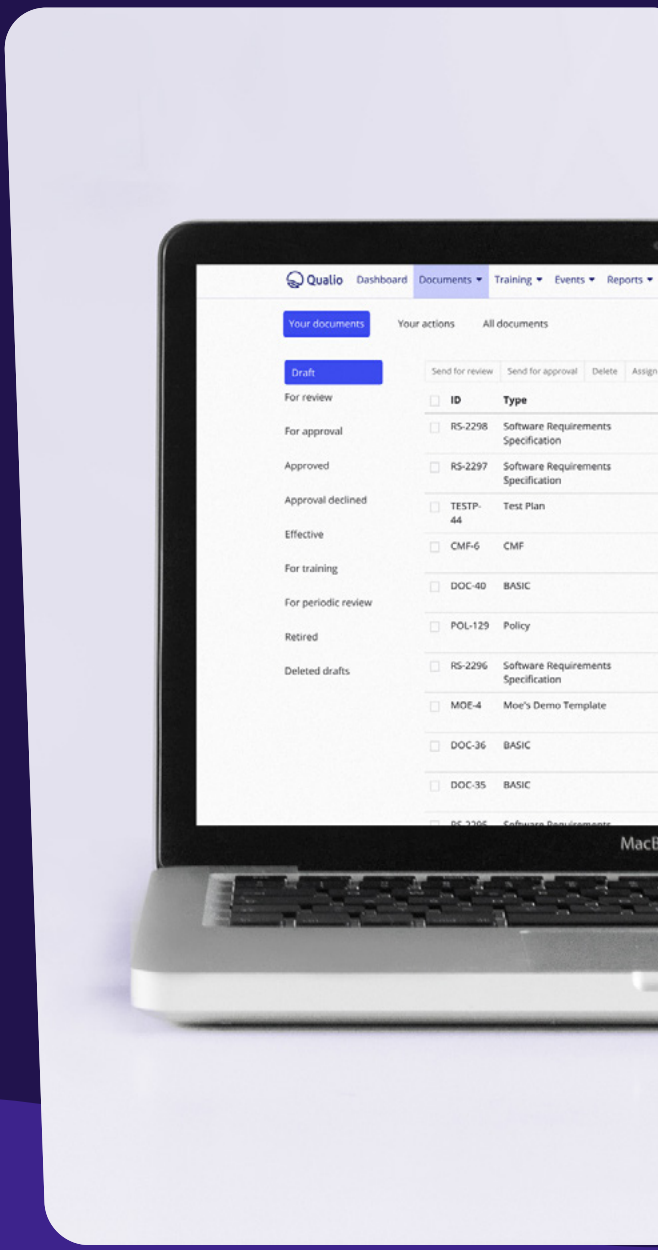
Purchasing	☐ Increased focus on supplier monitoring and risk ☐ Documented agreements for prior notification of changes to supplied product ☐ Linkage between verification of purchased product and change control
Production and service provision	☐ Qualification of infrastructure ☐ Analysis of service records ☐ Documented procedures for validation including statistical techniques, sampling rationale and revalidation ☐ Validation requirements for processes that cannot or are not subsequently monitored ☐ Procedures for risk based software validation ☐ Documented procedure for product identification/status during production; this may be Unique Device Identification (UDI) ☐ Validation of sterile barrier systems ☐ Suitability of packaging systems ☐ Recording of measuring equipment adjustments
Monitoring and measurement	☐ Linkages from customer feedback into risk management ☐ Documented processes for ascertaining whether customer requirements have been met ☐ Procedures for complaint handling ☐ Processes for informing third parties of complaints ☐ Plans for internal audits at defined intervals ☐ Processes for the identification of test equipment
Control of nonconforming product	☐ Processes for communication with external parties regarding non-conforming product ☐ Controls for managing concessions ☐ Linkages between rework and regulatory requirements
Analysis of data	☐ Sources of data for analysis, such as service records and audits ☐ Procedures that cover the application of statistical techniques ☐ Linkages between the analysis and improvement processes
Improvement	☐ Actions are taken without undue delay ☐ Evaluation of actions for adverse effects on regulatory requirements and product safety and performance

Qualio

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.

Request a demo today



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