PACIFIC CERTIFICATIONS

ISO 13485:2016 Audit Checklist

Medical Devices - Quality Management Systems

Website Download Resource

Use this template to review readiness against ISO 13485:2016 requirements for medical device quality management systems. The document is designed for internal preparation, documentation review and certification readiness planning.

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Accredited Certification Body Resource

Pacific Certifications provides independent third-party certification assessment and certification services. This resource is for general educational and readiness reference only and does not replace the formal requirements of ISO 13485:2016 or applicable regulatory obligations.

How to Use This Downloadable Template

This checklist helps organizations review ISO 13485:2016 conformity through clause-wise questions, evidence prompts and status tracking before certification assessment.

Field	Purpose	Suggested Use	Output
Requirement / Question	Identifies the ISO 13485 area being reviewed.	Read each row and compare it with your current QMS.	Clear assessment focus.
Evidence / Records	Captures documents, records and objective evidence.	List procedure numbers, records, forms, logs and system evidence.	Traceable evidence list.
Status	Tracks conformity or implementation maturity.	Use Conforming, Partial, Gap, Not Applicable or Needs Review.	Prioritized readiness view.
Action / Responsibility	Documents next action and owner.	Assign corrective or improvement actions with target dates.	Actionable follow-up plan.

ISO 13485:2016 Audit Checklist

Use the checklist below to review conformity readiness against ISO 13485:2016. Record evidence, observed status and remarks for each requirement area.

Clause 4 - Quality Management System

Clause	Audit Question	Evidence / Records Reviewed	Status	Remarks / Action
4.1	Are QMS processes identified, documented, implemented, maintained and controlled, including outsourced processes?			
4.2	Is the quality manual established and does it include scope, exclusions/non-applicability, procedures and process interaction?			
4.2	Are medical device files maintained for each device or device family, including specifications, manufacturing, installation and servicing information where applicable?			
4.2	Are document and record controls defined for approval, review, change control, retention and protection?			

Clause 5 - Management Responsibility

Clause	Audit Question	Evidence / Records Reviewed	Status	Remarks / Action
5.1	Does top management demonstrate commitment to QMS effectiveness and regulatory compliance?			
5.2	Are customer and applicable regulatory requirements determined and met?			
5.3	Is the quality policy appropriate, communicated and reviewed for continuing suitability?			
5.4	Are measurable quality objectives established and planned?			
5.5	Are responsibilities, authorities and internal communication arrangements defined?			
5.6	Are management reviews conducted at planned intervals with required inputs, outputs and follow-up actions?			

Clause 6 - Resource Management

Clause	Audit Question	Evidence / Records Reviewed	Status	Remarks / Action
6.2	Are competence needs determined for personnel affecting product quality and regulatory compliance?			
6.2	Are training records and effectiveness evaluations maintained?			
6.3	Is infrastructure maintained to achieve product conformity?			
6.4	Are work environment and contamination control requirements defined where relevant?			

Clause 7 - Product Realization

Clause	Audit Question	Evidence / Records Reviewed	Status	Remarks / Action
7.1	Is product realization planned with quality objectives, risk controls, documentation and acceptance criteria?			
7.2	Are customer and regulatory requirements reviewed before commitment to supply?			
7.3	Are design and development stages planned and controlled, including inputs, outputs, review, verification, validation, transfer and change control?			
7.4	Are suppliers evaluated, selected, monitored and re-evaluated based on their ability to meet specified requirements?			
7.5	Are production and service activities controlled through documented instructions, monitoring and validated processes where output cannot be verified later?			
7.5	Is identification and traceability maintained as required by product and regulatory requirements?			
7.5	Are installation, servicing, sterile barrier, preservation and cleanliness requirements controlled where applicable?			
7.6	Are monitoring and measuring devices calibrated or verified and protected from damage or invalid adjustment?			

Clause 8 - Measurement, Analysis and Improvement

Clause	Audit Question	Evidence / Records Reviewed	Status	Remarks / Action
8.2	Are feedback and complaint handling processes implemented and linked to risk management and			

	improvement?			
8.2	Are applicable regulatory reporting requirements identified and fulfilled?			
8.2	Is an internal audit program planned and conducted objectively?			
8.3	Is nonconforming product identified, controlled, segregated and dispositioned?			
8.4	Is data analyzed for suitability, effectiveness and improvement of the QMS?			
8.5	Are corrective and preventive actions controlled, investigated for root cause and checked for effectiveness?			

Summary and Action Plan

Priority	Gap / Finding	Related Clause	Responsible Person	Target Date

Ready for ISO 13485:2016 Certification?

Pacific Certifications provides independent certification assessment and internationally recognized certificate issuance support for eligible organizations. Email support@pacificcert.com to request the application form, certification cost estimate or next certification stage guidance.