PACIFIC CERTIFICATIONS

ISO 13485:2016 Gap Analysis Template

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 template helps organizations evaluate how well their quality management system addresses ISO 13485:2016 requirements for medical devices and related services.

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 Gap Analysis Matrix

Use the matrix below to compare current QMS arrangements with ISO 13485:2016 requirements. Mark each area as Conforming, Partial, Gap, Not Applicable or Needs Review, then assign actions where needed.

Clause 4 - Quality Management System

Clause	Requirement Area	Expected Evidence	Current Status	Gap / Risk	Action Owner / Date
4.1	General requirements and QMS processes	Quality manual, process map, interaction matrix, outsourced process controls			
4.2	Documentation requirements and medical device file	Documented procedures, quality manual, medical device files, record controls			

Clause 5 - Management Responsibility

Clause	Requirement Area	Expected Evidence	Current Status	Gap / Risk	Action Owner / Date
5.1-5.3	Management commitment, customer focus and quality policy	Quality policy, objectives, customer/regulatory requirements, leadership review			

5.4-5.6	Planning, responsibility, authority, communication and management review	Objectives, responsibilities, management review minutes, action follow-up records			

Clause 6 - Resource Management

Clause	Requirement Area	Expected Evidence	Current Status	Gap / Risk	Action Owner / Date
6.1-6.2	Resources, competence, awareness and training	Competence matrix, training records, effectiveness evaluations			
6.3-6.4	Infrastructure and work environment / contamination control	Maintenance records, environmental controls, cleanliness/contamination controls where applicable			

Clause 7 - Product Realization

Clause	Requirement Area	Expected Evidence	Current Status	Gap / Risk	Action Owner / Date
7.1	Planning of product realization	Realization plans, acceptance criteria, risk controls, validation requirements			
7.2	Customer-related processes	Customer requirements, regulatory requirements, contract review, communication records			
7.3	Design and development	Design plans, design inputs/outputs, reviews, verification, validation, design transfer, change records			
7.4	Purchasing and supplier controls	Supplier evaluation, approved supplier list, purchasing data, supplier monitoring			
7.5	Production and service provision	Work instructions, process validation, identification, traceability, preservation, installation/service records			

7.6	Control of monitoring and measuring equipment	Calibration records, equipment status, verification records			

Clause 8 - Measurement, Analysis and Improvement

Clause	Requirement Area	Expected Evidence	Current Status	Gap / Risk	Action Owner / Date
8.1-8.2	Feedback, complaint handling, reporting, internal audit and monitoring	Feedback records, complaint files, vigilance/reporting records, internal audit program			
8.3	Control of nonconforming product	Nonconformity records, concessions, segregation, advisory notices			
8.4	Analysis of data	Trend reports, supplier performance, process/product data, complaint trends			
8.5	Improvement, corrective action and preventive action	CAPA records, root cause analysis, effectiveness checks, preventive action records			

Summary and Action Plan

Priority	Gap / Finding	Related Clause	Responsible Person	Target Date