PACIFIC CERTIFICATIONS

ISO 13485:2016

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM

IMPLEMENTATION GUIDE

PLAN	DOCUMENT	CONTROL	VERIFY

A practical, clause-by-clause guide for planning, implementing, maintaining and improving a medical device Quality Management System.

Implementation status note

This guide is aligned with ISO 13485:2016 for medical device Quality Management Systems. Organizations should also consider applicable statutory and regulatory requirements in each target market.

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How to Use This Guide

This guide supports organizations involved in medical devices and related services in understanding and implementing ISO 13485:2016. It translates the standard into practical activities, example records, suggested responsibilities and certification readiness checks.

Important impartiality notice

This publication is general educational guidance. It does not replace the official ISO standard, regulatory law or a single mandatory implementation method. Each organization remains responsible for designing a QMS appropriate to its own devices, processes, regulatory markets and risks.

Contents

Guide conventions

- “Must” indicates an ISO 13485 requirement or a necessary control for the QMS to function effectively.
- “Should” indicates recommended good practice that may be adapted to the organization.
- Examples are illustrative and should be tailored to device type, risk class, regulatory markets and outsourced processes.

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Understanding ISO 13485

ISO 13485:2016 is a medical-device-specific quality management standard designed for organizations that need to consistently provide medical devices and related services that meet customer and applicable regulatory requirements.

Unlike ISO 9001, ISO 13485 places stronger emphasis on regulatory-purpose documentation, product realization controls, risk management, sterile-device controls, traceability, complaint handling and maintaining QMS effectiveness.

ISO 9001:2015	ISO 13485:2016
General quality management standard across all sectors.	Medical-device QMS standard for regulatory purposes.
Customer satisfaction and continual improvement are major themes.	Regulatory compliance and QMS effectiveness are major themes.
More flexibility in required documented information.	More explicit documented procedures and retained records.
General risk-based thinking.	Risk management linked to product realization and medical-device safety.
No specific medical-device file requirement.	Medical device files required for each device type or family.

Who can use ISO 13485?

- Medical device manufacturers and design organizations.
- Contract manufacturers, component suppliers and service providers.
- Sterilization, installation, servicing, storage, distribution and import organizations.
- Organizations supporting the medical-device life cycle under customer or regulatory obligations.

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Implementation Roadmap

Implementation should be treated as a controlled project. A medical-device QMS must be supported by actual records, trained personnel and evidence of process operation, not only manuals and procedures.

Phase	Key actions	Typical outputs
1. Scope and planning	Define device families, sites, outsourced processes and regulatory markets.	QMS scope, process map, regulatory matrix.
2. Gap analysis	Compare current controls against ISO 13485 and applicable regulations.	Gap report and implementation action plan.
3. Documentation	Prepare quality manual, procedures, forms and device-file structure.	Controlled documentation and master list.
4. Implementation	Train personnel and operate design, purchasing, production, traceability and CAPA controls.	Training, production, supplier and CAPA records.
5. Verification	Complete internal audit, correction, CAPA and management review.	Audit report, CAPA log, management review minutes.

Suggested implementation principles

- Start with regulatory requirements and intended markets before drafting procedures.
- Keep documentation simple but controlled, complete and traceable.
- Make every procedure reflect actual practice rather than generic template text.
- Retain objective evidence for each critical process before planning certification assessment.

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Clause 4: Quality Management System

Clause 4 requires the organization to document, implement and maintain the QMS and keep it effective. The organization must identify processes, sequence, interaction, criteria, resources, monitoring methods and outsourced process controls.

Requirement area	Implementation guidance	Evidence examples
QMS scope	Define device types, activities, sites, regulatory markets and any justified non-applicability.	Scope statement, process map, regulatory matrix.
Quality manual	Document or reference procedures and process interactions.	Controlled quality manual, procedure index.
Medical device file	Maintain file for each type or family of medical device.	Device specifications, production, packaging, storage and servicing references.
Document control	Control approval, review, change status, distribution and obsolete documents.	Document procedure, master list, change history.
Record control	Control identification, storage, protection, retrieval, retention and disposition.	Record matrix, completed forms, retention schedule.
Outsourced processes	Control outsourced activities that affect conformity.	Supplier agreements, monitoring records, purchasing data.

Implementation tip

Medical device files do not need to duplicate every record. They may contain or reference the records and documents needed to prove that the device type or family is controlled.

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Clause 5: Management Responsibility

Top management must provide visible leadership, ensure customer and regulatory requirements are met, approve the quality policy, set measurable quality objectives, define responsibility and authority, and conduct management review.

Requirement	Implementation guidance	Evidence examples
Management commitment	Communicate the importance of meeting customer and regulatory requirements.	Leadership communications, resource approvals.
Customer focus	Determine customer and regulatory requirements before commitment.	Contract review, regulatory review, change review.
Quality policy	Approve a policy suitable for medical-device regulatory requirements.	Signed policy and communication evidence.
Quality objectives	Set measurable objectives at relevant functions and levels.	KPI tracker and objective reviews.
Responsibility and authority	Define roles and management representative responsibilities.	Organization chart, role matrix, job descriptions.
Management review	Review QMS effectiveness and required actions.	Agenda, inputs, outputs and action tracker.

Management review should include feedback, complaints, audit results, process performance, product conformity, CAPA, regulatory changes, supplier performance, resource needs and improvement opportunities.

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Clause 6: Resource Management

The organization must determine and provide resources needed to implement and maintain the QMS, maintain effectiveness and meet customer and applicable regulatory requirements.

Resource area	Controls to consider
Competence	Training matrix, qualification criteria, awareness, job-specific training and competence verification.
Infrastructure	Facilities, utilities, equipment, software, preventive maintenance, backup and validation where applicable.
Work environment	Cleanliness, contamination control, gowning, ESD, humidity, temperature and biological safety controls where relevant.
Monitoring and measuring equipment	Calibration, verification, status identification, protection, traceability and out-of-tolerance actions.
Personnel health and hygiene	Controls where personnel condition can affect product quality or contamination risk.

Competence and awareness controls

- Define competence requirements for each role affecting product quality.
- Train operators, inspectors, design personnel, sterilization-related roles, complaint handlers and internal auditors.
- Verify competence through observation, testing, supervisor sign-off or qualification records.
- Retain evidence of education, training, skills and experience.

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Clause 7: Product Realization

Product realization must be planned and controlled. Planning should define device requirements, regulatory requirements, risk controls, resources, verification, validation, acceptance criteria, traceability and records.

Planning element	Questions to answer
Product requirements	What customer, intended-use, safety, performance, labelling and regulatory requirements apply?
Process requirements	What production, cleanroom, sterilization, packaging, storage, installation or service processes are required?
Risk controls	Which risk controls are required by design, production, labelling, suppliers or post-market processes?
Verification and validation	What inspections, tests, validations, software checks or process validations are required?
Records	Which records must be retained to prove conformity and traceability?

- Customer-related requirements must be reviewed before the organization commits to supply.
- Changes in customer or regulatory requirements must be controlled and communicated.
- The organization must maintain communication channels for product information, enquiries, contracts, feedback and complaints.

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Design and Development Controls

Where design and development is applicable, it must be planned and controlled from design inputs through outputs, reviews, verification, validation, transfer and change control. If design and development is not applicable, the justification must be documented and supported by regulatory requirements and actual responsibilities.

Design stage	Implementation focus	Records
Planning	Define stages, responsibilities, review points and interfaces.	Design plan, responsibility matrix.
Inputs	Capture intended use, performance, safety, regulatory and risk-control requirements.	Design input record, regulatory input, risk file.
Outputs	Produce specifications, drawings, BOM, procedures and acceptance criteria.	Design output package, device file references.
Review	Evaluate design progress and ability to meet requirements.	Review minutes and action records.
Verification	Confirm outputs meet inputs.	Test reports, inspection reports.
Validation	Confirm device meets intended use and user needs.	Validation protocol and report.
Transfer	Ensure production can reproduce the design.	Transfer checklist, production readiness records.
Changes	Evaluate change impact on risk, regulatory, design and production controls.	Change request, approvals, re-verification or re-validation.

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Purchasing and Supplier Controls

Purchasing controls must be proportionate to the effect of purchased product or outsourced processes on device quality and regulatory compliance. Critical suppliers need stronger qualification and monitoring controls.

Supplier control step	Purpose	Evidence
Supplier evaluation	Select suppliers based on ability to meet requirements.	Evaluation checklist, qualification records.
Purchasing information	Communicate product, process, approval and regulatory requirements.	Purchase order, specification, quality agreement.
Verification of purchased product	Confirm purchased product meets requirements.	Incoming inspection, COA review, test records.
Supplier monitoring	Review ongoing performance and issues.	Scorecards, NCRs, corrective actions.
Outsourced process control	Control processes performed externally, including sterilization, calibration, special processes or software services.	Agreements, validation evidence, monitoring results.

- Classify suppliers by risk and impact on device conformity.
- Define controls in purchasing information before release of purchase orders.
- Retain records of supplier evaluation, selection, monitoring and re-evaluation.

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Production and Service Provision

Production and service provision must be carried out under controlled conditions. The level of control depends on the device, process risk, regulatory requirements, outsourced activities and validation needs.

Control area	Examples of implementation evidence
Work instructions	Approved production, inspection, cleaning, packaging, labelling, installation and servicing instructions.
Equipment controls	Preventive maintenance, equipment qualification, calibration and equipment-status identification.
Process validation	Validated special processes where results cannot be fully verified by later inspection or testing.
Product identification	Lot, batch, serial number, UDI or other identification method as applicable.
Status identification	Clear indication of inspection, test, quarantine, release or rejection status.
Customer property	Protection of customer-owned materials, drawings, data, tools or samples.
Preservation	Controls for handling, packaging, storage, contamination, shelf life and transportation.

Process validation note

Processes such as sterilization, welding, sealing, bonding, cleaning, software-controlled production or automated inspection may require validation when output cannot be fully verified by subsequent monitoring or measurement.

11 Risk Management and Regulatory Controls

ISO 13485 expects a risk-based approach throughout product realization. Risk management should be connected to design, purchasing, production, installation, servicing, feedback, complaints and CAPA.

Risk control area	Implementation focus
Risk management plan	Define responsibilities, criteria, methods, review points and records.
Hazard identification	Identify hazards from intended use, reasonably foreseeable misuse, production, installation and service.
Risk evaluation	Assess severity and probability using defined criteria.
Risk controls	Apply inherent safety, protective measures and information for safety where applicable.
Residual risk	Evaluate residual risk and acceptability after controls.
Production/post-production information	Use complaints, feedback, service data and nonconformities to update risk controls.
Regulatory compliance	Maintain a register of applicable laws, registration, labelling, reporting and market requirements.

- Risk files should be device-specific or device-family-specific where practical.
- Risk control measures should be traceable to verification, validation, production or labelling evidence.
- Regulatory reporting decisions should be documented according to applicable market requirements.

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Traceability, Cleanliness and Sterile Controls

Traceability, cleanliness and sterile-device controls must be defined where applicable to the device, process and regulatory requirements. These controls are often examined closely during certification assessment.

Requirement area	Controls to define
Traceability	Lot, batch, serial number, UDI, components, materials, processing steps, released quantities and distribution information.
Implantable devices	Additional traceability for components, materials, work environment conditions and personnel where required.
Cleanliness	Cleaning methods, cleanliness acceptance criteria, contamination prevention and cleaning validation where applicable.
Contamination control	Segregation, gowning, environmental monitoring, bioburden controls and handling controls.
Sterile medical devices	Sterilization validation, batch release, sterility assurance and sterile barrier controls.
Installation and servicing	Installation records, service reports, acceptance criteria and service feedback links.

13 Feedback and Complaints

The organization must establish a feedback system to provide early warning of quality problems and input into corrective and preventive action. Complaint handling must be structured, documented and connected to regulatory reporting decisions.

Process	Implementation focus
Feedback	Collect information from customers, users, distributors, service activities, regulatory authorities and production/post-production sources.
Complaint intake	Record complaint details, device identification, event description, customer information and initial risk assessment.
Complaint investigation	Determine whether investigation is required, document justification where not investigated and retain results.
Regulatory reporting decisions	Evaluate whether the complaint requires notification to authorities according to applicable regulations.
Trend analysis	Review recurring complaints, service issues, nonconformities or adverse trends.
Risk review	Feed complaint and post-market data into risk management and CAPA processes.

- Complaint records must be retained even when investigation is not performed; the justification must be documented.
- Complaints involving possible failure to meet specifications must be evaluated for investigation and regulatory reporting.
- Feedback information should be analyzed as an input to improvement and management review.

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Measurement, Analysis and Improvement

The organization must monitor, measure, analyze and improve the QMS to ensure product conformity and maintain effectiveness. This includes internal audit, monitoring and measurement, control of nonconforming product, data analysis and corrective/preventive action.

Activity	Good implementation practice	Evidence
Internal audit	Audit processes at planned intervals using competent independent auditors.	Audit programme, plan, report, findings and closure.
Process monitoring	Monitor product, process and supplier performance indicators.	KPI tracker, trend charts, review minutes.
Nonconforming product	Identify, segregate, evaluate, disposition and record product not meeting requirements.	NCR, disposition approval, concession record.
Corrective action	Investigate root cause, implement action and verify effectiveness.	CAPA form, 5 Why/Fishbone, action evidence.
Preventive action	Identify potential nonconformities and take action to prevent occurrence.	Risk review, preventive action record.
Management review	Evaluate QMS suitability, adequacy and effectiveness.	Management review minutes and action tracker.

Effectiveness check

A CAPA is not closed only because an action was completed. Closure should include evidence that the action was effective and did not introduce new risks or nonconformities.

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Documented Information Toolkit

The following toolkit provides a practical starting point. The organization should adapt the list to its device type, regulatory markets, outsourced processes and activities performed.

Document / record	Purpose
Quality manual	Defines scope, processes, exclusions/non-applicability and documented procedures.
Regulatory requirements register	Maps applicable laws, market requirements and regulatory responsibilities.
Risk management procedure and risk file	Controls product risk planning, risk evaluation, risk control and residual risk review.
Medical device file	Maintains device-specific specifications and realization information.
Design and development procedure	Controls design inputs, outputs, review, verification, validation, transfer and changes.
Supplier control procedure	Controls supplier evaluation, purchasing information and supplier monitoring.
Production and process control procedure	Defines work instructions, inspections, release and operational controls.
Process validation procedure	Controls IQ/OQ/PQ, validation reports, revalidation and change impact.
Traceability procedure	Controls identification, status and lot/serial/UDI traceability.
Complaint handling procedure	Controls complaint intake, investigation, regulatory reporting evaluation and closure.
CAPA procedure	Controls root cause, actions and effectiveness verification.
Internal audit and management review procedure	Controls performance evaluation and leadership review.

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Certification Readiness Checklist

Readiness item	Status	Evidence reference
QMS scope approved and aligned with device activities	Yes / No / NA	Evidence / comment
Quality manual controlled and current	Yes / No / NA	Evidence / comment
Process map and interactions defined	Yes / No / NA	Evidence / comment
Regulatory requirements register maintained	Yes / No / NA	Evidence / comment
Medical device file prepared for each device family	Yes / No / NA	Evidence / comment
Risk management file linked to product realization	Yes / No / NA	Evidence / comment
Design and development records complete or justified as not applicable	Yes / No / NA	Evidence / comment
Supplier evaluation and monitoring records available	Yes / No / NA	Evidence / comment
Production controls and release records available	Yes / No / NA	Evidence / comment
Process validations completed where required	Yes / No / NA	Evidence / comment
Traceability records defined and retained	Yes / No / NA	Evidence / comment
Complaint handling process implemented	Yes / No / NA	Evidence / comment
Feedback and post-market information analyzed	Yes / No / NA	Evidence / comment
NCR and CAPA processes operating	Yes / No / NA	Evidence / comment
Internal audit completed	Yes / No / NA	Evidence / comment
Management review completed	Yes / No / NA	Evidence / comment
Training and competence evidence available	Yes / No / NA	Evidence / comment
Calibration/verification records available	Yes / No / NA	Evidence / comment
Record retention requirements defined	Yes / No / NA	Evidence / comment
Personnel can explain actual process responsibilities	Yes / No / NA	Evidence / comment

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90-Day Implementation Planner

Timeframe	Focus area	Actions
Days 1-15	Scope and regulatory mapping	Confirm scope, device families, outsourced processes, regulatory markets and project team.
Days 16-30	Gap analysis and document planning	Compare current system against ISO 13485, applicable regulations and device life-cycle processes.
Days 31-45	Core documentation	Prepare quality manual, procedures, forms, medical device file structure and record controls.
Days 46-60	Operational implementation	Train personnel and operate purchasing, production, design, traceability, complaint and CAPA processes.
Days 61-75	Internal audit and corrections	Audit the full QMS, document findings, correct gaps and update records.
Days 76-90	Management review and readiness	Complete management review, close high-risk findings and prepare objective evidence for certification.

- Do not schedule certification assessment before operational records are available.
- Ensure records prove actual implementation, not only procedure availability.
- Verify that regulatory requirements are identified for every applicable market and device type.

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Frequently Asked Questions

Is ISO 13485 only for manufacturers?

No. It can apply to organizations involved in design, production, installation, servicing, storage, distribution, import and related services for medical devices.

Can design and development be excluded?

Only when permitted by applicable regulatory requirements and when the organization is not responsible for design and development. The justification should be documented.

Is ISO 13485 the same as ISO 9001?

No. ISO 13485 is specific to medical devices and focuses on regulatory-purpose quality management. It contains additional medical-device controls and excludes some ISO 9001 concepts that are not appropriate as regulatory requirements.

What evidence is most important for certification readiness?

Controlled documents must match actual practice, and records should prove operation of design, purchasing, production, traceability, validation, complaint handling, CAPA, internal audit and management review processes.

Does Pacific Certifications implement the QMS for clients?

Pacific Certifications performs independent assessment and certification activities. Organizations remain responsible for implementation and maintenance of their own QMS.

Reference standards to consider

Organizations often use ISO 14971 for medical device risk management and related regulatory requirements for device classification, registration, labelling, UDI, post-market surveillance and vigilance. Applicability depends on device type and target markets.

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About Pacific Certifications

Pacific Certifications is an independent certification body supporting organizations with management system certification and related certification information. This guide is intended to help organizations understand implementation requirements before certification assessment.

For ISO certification information, application forms, certification process details and cost guidance, organizations may contact Pacific Certifications at support@pacificcert.com or visit www.pacificcert.com.

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