MANUFACTURING PLUS

Quality system content list

Review the documents included in this package, organized by quality-system activity. Use the document IDs to locate the corresponding files in your download.

73 procedures listed | Editable quality-system documentation

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QMSR*
QMSM	Quality Management System Manual (QMSM)	All	820.10(a)

4.0 Quality Management System

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QMSR*
LIST 0001	Master List of Quality System Operating Procedures	4.2.2	820.10(a)
LIST 0002	External Standards List	4.2.4	820.10(a)
SOP 4-001	Engineering Change Notice (ECN) Procedure	4.2.4	820.10(a)
SOP 4-002	Document Control Procedure	4.2.4	820.10(a)
SOP 4-003	Record Retention Procedure	4.2.5	820.35
SOP 4-004	External Standards Procedure	4.2.4	820.10(a)
SOP 4-005	Good Documentation Practices	-	820.10(a)
SOP 4-006	Specification Format Procedure	4.2.1	820.10(a)
SOP 4-007	Device Master Record	4.2.3	820.10(a)

5.0 Management Responsibility

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QMSR*
SOP 5-001	Management Review Procedure	5.6.1, 5.6.2, 5.6.3, 6.1, 8.5	820.10(a)
SOP 5-002	Organization, Responsibilities, and Authority	5.5.1, 5.5.2	820.10(a)

6.0 Resource Management

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QMSR*
SOP 6-001	Training & Job description Procedure	6.1, 6.2	820.10(a)
SOP 6-002	Respiratory Protection Procedure	6.4.1	820.10(a)
SOP 6-003	Biohazard and Waste Disposal	6.4.1, 6.4.2	820.10(a)
SOP 6-004	Lockout / Tagout Procedure	6.4.1	820.10(a)
SOP 6-005	Controlled Environment Gowning	6.4.1, 6.4.2	820.10(a)
SOP 7-013	Environmental Controls Procedure	6.4, 7.5.1, 7.5.2	820.10(a)
SOP 7-016	Preventive Maintenance Procedure	6.3, 7.5.1	820.10(a)
SOP 7-018	Controlled Environment Cleaning Procedure	6.4, 7.5.1, 7.5.2	820.10(a)

7.0 Product Realization

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QMSR*
LIST 0004	Approved Supplier List	7.4.1, 7.5.1	820.10(a)
SOP 7-001	Design Control Procedure	7.3.1-7.3.8	820.10(c)
SOP 7-002	Design Review Procedure	7.3.1-7.3.7	820.10(c)
SOP 7-003	Risk Management Procedure	7.3.1-7.3.9, 8.2.1	820.10(a)
SOP 7-004	Contract Review Procedure	7.2.1, 7.2.2, 7.2.3	820.10(a)
SOP 7-005	Purchase Order Procedure	7.4.1, 7.4.2, 7.4.3	820.10(a)
SOP 7-006	Supplier Management Procedure	7.4.1, 7.5.1	820.10(a)
SOP 7-007	Identification Procedure	7.5.8	820.10(a)
SOP 7-008	Receiving Procedure	7.5.8	820.10(a)
SOP 7-009	Calibration System Procedure	7.6	820.10(a)
SOP 7-010	Finished Goods Shipping Procedure	7.5.1, 7.5.8	820.10(a)
SOP 7-011	Lot Inspection Procedure	7.5.8	820.10(a)
SOP 7-012	Process Validation Procedure	7.5.6	820.10(a)
SOP 7-014	Installation Qualification Procedure	7.5.1, 7.5.6	820.10(a)
SOP 7-015	Protocols and Reports Procedure	7.5.6	820.10(a)

7.0 Product Realization

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QMSR*
SOP 7-017	First Article Inspection Procedure	7.4.3	820.10(a)
SOP 7-019	Device History Record Procedure	4.2.5, 7.5.8, 7.5.9	820.10(a)
SOP 7-020	Line Clearance Procedure	7.5.1	820.10(a)
SOP 7-021	Design Transfer Procedure	7.3.8	820.10(c)
SOP 7-022	Design Change Procedure	7.3.9	820.10(c)
SOP 7-023	Sterile Load Preparation and Release	7.5.1, 7.5.5, 7.5.9	820.10(a)
SOP 7-024	Technology Transfer Procedure	7.3.8	820.10(a)
SOP 7-025	Returned Goods Procedure	7.5.8	820.10(a)
SOP 7-026	Product Stability (Shelf Life) Procedure	7.3	820.10(a)
SOP 7-027	Labeling Review and Approval Procedure	7.3	820.45
SOP 7-028	Product Performance Specifications	7.3	820.10(c)
SOP 7-029	Design Verification and Validation Procedure	7.3.7	820.10(c)
SOP 7-030	Design Risk Management Procedure	7.3, 8.2.1	820.10(c)
SOP 7-031	Process Risk Management Procedure	7.3, 8.2.1	820.10(a)
SOP 7-032	Design Analysis Procedure	7.3, 8.2.1	820.10(c)
SOP 7-033	Software Validation Procedure	7.5.6	820.10(a)
SOP 7-034	Biocompatibility and Toxicity Testing Procedure	7.3, 7.5.1, 7.5.2	820.10(a)
SOP 7-035	Ethylene Oxide Sterilization Validation Procedure	7.5.6, 7.5.7	820.10(a)
SOP 7-036	Gamma Irradiation Validation and Monitoring	7.5.6, 7.5.7	820.10(a)
SOP 7-037	Unique Device Identification (UDI) Procedure	7.3.3	820.10(b)(1)
SOP 7-038	Clinical Evaluations Procedure	MDR, 8.2, 8.2.3	820.10(a)
SOP 7-039	Clinical Investigation Procedure	MDR, 8.2,8.2.3	820.10(a)
SOP 7-040	CE Marking Procedure	4.2.3, 7.3.10	-
SOP 7-041	Injection Mold Validation Procedure	7.5.6	820.10(a)
SOP 7-042	Human Factors and Usability Engineering Procedure	7.3.1-7.3.8	820.10(c)

7.0 Product Realization

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QMSR*
SOP 7-043	Software Development Procedure	7.3.1-7.3.8	820.10(c)
SOP 7-044	Software Clinical Evaluation Procedure	7.3.1-7.3.8	820.10(c)
SOP 7-045	Cleanroom Design and Validation Procedure	6.4, 7.5.1, 7.5.2	820.10(a)
SOP 7-046	Customer Requirements Validation Procedure	7.3.1-7.3.8	820.10(c)

8.0 Measurement, Analysis And Improvement

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QMSR*
SOP 8-001	Complaint Handling Procedure	8.2.1, 8.2.2, 8.2.3	820.35(a)
SOP 8-002	Complaint Trending Procedure	8.2.1, 8.2.2, 8.2.3	820.35(a)
SOP 8-003	Remedial Action / Recall Procedure	8.2.3	820.10(b)(4)
SOP 8-004	Corrective and Preventive Action System	8.5.2, 8.5.3	820.10(a)
SOP 8-005	Internal Audit Procedure	8.2.4	820.10(a)
SOP 8-006	Medical Device Reports (MDR) Procedure	-	820.10(b)(3)
SOP 8-007	Statistical Techniques Procedure	8.4	820.10(a)
SOP 8-008	Non-Conforming Material System Procedure	8.3	820.10(a)
SOP 8-009	Vigilance Report Procedure	MDR, 8.2.2, 8.2.3	-
SOP 8-010	Product Hold Procedure	8.3	820.10(a)
SOP 8-012	Post-Market Surveillance	MDR, 8.2.1, 8.2.3	820.10(a)
SOP 8-013	Periodic Safety Update Report Procedure	MDR	-
SOP 8-014	Failure Investigation Procedure	8.2.1, 8.2.2, 8.2.3	820.35(a)

* FDA QMSR references updated 09/30/2026. See current-framework notes on the final page.
ISO references and source appendix remain topical guides, not a verified compliance crosswalk.

Reference appendix

Source regulatory cross-reference

This appendix preserves the source mapping between quality-system clauses and documents. References are provided for review and have not been assessed for current regulatory accuracy.

4.0 Quality Management System

CLAUSE	SOURCE DESCRIPTION	DOCUMENT / SOP
4.1	General requirements	QMSM
4.2	Documentation requirements [title only]	[title only]
4.2.1	General	QMSM
4.2.2	Quality Manual	QMSM, LIST 0001
4.2.3	Medical Device File	SOP 4-007
4.2.4	Control of documents	QMSM, LIST 0002, SOP 4-001, SOP 4-002, SOP 4-004
4.2.5	Control of quality records	QMSM, SOP 4-003, SOP 4-005, SOP 7-019

5.0 Management Responsibility

CLAUSE	SOURCE DESCRIPTION	DOCUMENT / SOP
5.1	Management commitment	QMSM, SOP 6-001
5.2	Customer focus	QMSM
5.3	Quality policy	QMSM
5.4	Planning [title only]	[title only]
5.4.1	Quality objectives	[PROCEDURE NOT INCLUDED]
5.4.2	Quality planning	[PROCEDURE NOT INCLUDED]
5.5	Responsibilities, Authority and Communication [title only]	[title only]
5.5.1	Responsibility and authority	QMSM, SOP 5-002, ORG CHART
5.5.2	Management representative	QMSM, SOP 5-001, SOP 5-002
5.5.3	Internal communication	QMSM
5.6	Management Review [title only]	[title only]

5.0 Management Responsibility

CLAUSE	SOURCE DESCRIPTION	DOCUMENT / SOP
5.6.1	General	QMSM, SOP 5-001
5.6.2	Review input	QMSM, SOP 5-001
5.6.2	Review output	QMSM, SOP 5-001

6.0 Resource Management

CLAUSE	SOURCE DESCRIPTION	DOCUMENT / SOP
6.1	Provision of resources	QMSM, SOP 5-001
6.2	Human resources [title only]	[title only]
6.2.1	General	QMSM, SOP 6-001
6.2.2	Competence, Awareness and Training	QMSM, SOP 6-001
6.3	Infrastructure	QMSM, SOP 7-016
6.4	Work environment and contamination control	QMSM, SOP 6-002, SOP 6-003, SOP 6-004, SOP 6-005, SOP 7-013, SOP 7-018

7.0 Product Realization

CLAUSE	SOURCE DESCRIPTION	DOCUMENT / SOP
7.1	Planning of product realization	QMSM, SOP 7-001, SOP 7-002, SOP 7-003, SOP 7-028
7.2	Customer related processes [title only]	[title only]
7.2.1	Determination of requirements related to the product	QMSM, SOP 7-001, SOP 7-002, SOP 7-004, SOP 7-027, SOP 7-040
7.2.2	Review of requirements related to the product	QMSM, SOP 7-004
7.2.3	Customer communication	QMSM, SOP 7-004, SOP 8-001, SOP 8-003, SOP 8-010, SOP 8-012
7.3	Design and Development [title only]	[title only]
7.3.1	General	QMSM
7.3.2	Design and development planning	QMSM, SOP 7-001
7.3.3	Design and development inputs	QMSM, SOP 7-001, SOP 7-003
7.3.4	Design and development outputs	QMSM, SOP 7-001

7.0 Product Realization

CLAUSE	SOURCE DESCRIPTION	DOCUMENT / SOP
7.3.5	Design and development review	QMSM, SOP 7-001, SOP 7-002
7.3.6	Design and development verification	QMSM, SOP 7-029
7.3.7	Design and development validation	QMSM, SOP 7-029
7.3.8	Design and development transfer	QMSM, SOP 7-021
7.3.9	Control of design and development changes	QMSM, SOP 4-001, SOP 4-002, SOP 7-001, SOP 7-022
7.3.10	Design and development files	QMSM, SOP 7-001
7.4	Purchasing [title only]	[title only]
7.4.1	Purchasing process	QMSM, LIST 0004, SOP 7-006
7.4.2	Purchasing information	QMSM, LIST 0004, SOP 7-005
7.4.3	Verification of purchased product	QMSM, SOP 7-005, SOP 7-008, SOP 7-011, SOP 7-012, SOP 7-017, SOP 7-023, SOP 7-034, SOP 7-035, SOP 7-036, SOP 8-007
7.5	Production and service provision [title only]	[title only]
7.5.1	Control of production and service provision	QMSM, SOP 7-006, SOP 7-007, SOP 7-009, SOP 7-011, SOP 7-012, SOP 7-019, SOP 7-020, SOP 7-023, SOP 7-034, SOP 8-007
7.5.2	Cleanliness of product	QMSM, SOP 7-001, SOP 7-003
7.5.3	Installation activities	[PROCEDURE NOT INCLUDED]
7.5.4	Servicing activities	[PROCEDURE NOT INCLUDED]
7.5.5	Particular requirements for medical devices	QMSM, SOP 7-005, SOP 7-019, SOP 7-023
7.5.6	Validation of processes for production and service provision	QMSM, SOP 7-012, SOP 7-014, SOP 7-015, SOP 7-033, SOP 7-035, SOP 7-036, SOP 8-007
7.5.7	Particular requirements for validation of process for sterilization and sterile barrier systems	QMSM, SOP 7-013, SOP 7-026, SOP 7-034, SOP 7-035, SOP 7-036
7.5.8	Identification	QMSM, SOP 7-007
7.5.9	Traceability [title only]	[title only]
7.5.9.1	Traceability general	QMSM, SOP 7-004, SOP 7-007, SOP 7-008, SOP 7-010, SOP 7-011, SOP 7-019, SOP 7-023, SOP 8-008

7.0 Product Realization

CLAUSE	SOURCE DESCRIPTION	DOCUMENT / SOP
7.5.9.2	Particular requirements for active medical devices and implantable medical devices	QMSM, SOP 7-004, SOP 7-011, SOP 7-013, SOP 7-018, SOP 7-019
7.5.10	Customer property	[PROCEDURE NOT INCLUDED]
7.5.11	Preservation of product	QMSM, SOP 7-001, SOP 7-010, SOP 7-013 [MAY REQUIRE ADDITIONAL PRODUCT SPECIFIC PROCEDURE]
7.6	Control of monitoring and measurement devices	QMSM, SOP 7-009

8.0 Measurement, Analysis And Improvement

CLAUSE	SOURCE DESCRIPTION	DOCUMENT / SOP
8.1	General	QMSM, SOP 8-007
8.2	Monitoring and feedback [title only]	[title only]
8.2.1	Feedback	QMSM, SOP 7-003, SOP 8-012
8.2.2	Complaint handling	QMSM, SOP 8-001, SOP 8-002
8.2.3	Reporting to regulatory authorities	QMSM, SOP 8-003, SOP 8-006, SOP 8-009, SOP 8-013
8.2.4	Internal audit	QMSM, SOP 8-005
8.2.5	Monitoring and measurement of processes	QMSM, SOP 5-001, SOP 7-011, SOP 7-012, SOP 8-004, SOP 8-005, SOP 8-007
8.2.6	Monitoring and measurement of product	QMSM, SOP 7-001, SOP 7-002, SOP 7-011, SOP 7-021, SOP 7-029,
8.3	Control of nonconforming product	QMSM, SOP 8-008
8.4	Analysis of data	QMSM, SOP 8-007
8.5	Improvement [title only]	[title only]
8.5.1	General	QMSM, SOP 8-001, SOP 8-002, SOP 8-003
8.5.2	Corrective action	QMSM, SOP 8-004
8.5.3	Preventive action	QMSM, SOP 8-004

MANUFACTURING PLUS

Current FDA reference notes

Public content-list reference update: September 30, 2026. This update changes the public PDF references only. The original document IDs, titles, package counts, product links and source control identifiers are retained.

FDA's Quality Management System Regulation (QMSR) took effect February 2, 2026. Under 21 CFR 820.10(a), manufacturers must document a QMS meeting the applicable requirements of ISO 13485:2016 and the other applicable provisions of Part 820.

How to read the QMSR column

820.10(a) identifies the general QMS framework. It is not a one-to-one replacement for a legacy QSR section.

820.10(c) identifies design and development requirements for devices within that provision's scope. Review device classification and applicability.

820.35 / 820.35(a) identify supplemental records and complaint-record provisions. Applicability depends on the records and activities involved.

820.45 identifies supplemental device labeling and packaging controls.

820.10(b)(1), (b)(3), and (b)(4) point to UDI (Part 830), medical device reporting (Part 803), and corrections/removals (Part 806), respectively.

A dash means no FDA-specific supplemental citation is assigned here; it does not mean that all FDA requirements are inapplicable.

Scope of this update
The ISO clause column and any source appendix remain topical source guides; they have not been revalidated as a complete compliance crosswalk. These citations do not establish package completeness, regulatory compliance or certification. Confirm applicability and any additional requirements for your devices, activities and markets. Purchased ZIP files were not edited or audited in this update.

Official sources
FDA: Quality Management System Regulation
eCFR: current 21 CFR Part 820