# DESIGN 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.

45 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 7-016 | Preventive Maintenance Procedure | 6.3, 7.5.1 | 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 7-006 | Supplier Management Procedure | 7.4.1, 7.5.1 | 820.10(a) |
| SOP 7-009 | Calibration System Procedure | 7.6 | 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) |
| SOP 7-017 | First Article Inspection Procedure | 7.4.3 | 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 7-026 | 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) |

## 7.0 Product Realization

| DOCUMENT ID | DOCUMENT TITLE | ISO 13485 | QMSR* |
|---|---|---|---|
| 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) |
| SOP 7-043 | Software as a Medical Device 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 7-046 | 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 8-004 | Corrective and Preventive Action System | 8.5.2, 8.5.3 | 820.10(a) |
| SOP 8-007 | Statistical Techniques Procedure | 8.4 | 820.10(a) |
| 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.

# DESIGN 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