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	QSR*
QMSM	Quality Management System Manual (QMSM)	All	820.5

4.0 Quality Management System

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QSR*
LIST 0001	Master List of Quality System Operating Procedures	4.2.2	-
LIST 0002	External Standards List	4.2.4	820.40
SOP 4-001	Engineering Change Notice (ECN) Procedure	4.2.4	820.40
SOP 4-002	Document Control Procedure	4.2.4	820.40
SOP 4-003	Record Retention Procedure	4.2.5	820.180
SOP 4-004	External Standards Procedure	4.2.4	820.40
SOP 4-005	Good Documentation Practices	-	-
SOP 4-006	Specification Format Procedure	4.2.1	820.181
SOP 4-007	Device Master Record	4.2.3	820.181

5.0 Management Responsibility

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QSR*
SOP 5-001	Management Review Procedure	5.6.1, 5.6.2, 5.6.3, 6.1, 8.5	820.20
SOP 5-002	Organization, Responsibilities, and Authority	5.5.1, 5.5.2	820.20

6.0 Resource Management

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QSR*
SOP 6-001	Training & Job description Procedure	6.1, 6.2	820.25
SOP 7-016	Preventive Maintenance Procedure	6.3, 7.5.1	820.70

7.0 Product Realization

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QSR*
LIST 0004	Approved Supplier List	7.4.1, 7.5.1	820.50
SOP 7-001	Design Control Procedure	7.3.1-7.3.8	820.30
SOP 7-002	Design Review Procedure	7.3.1-7.3.7	820.30
SOP 7-003	Risk Management Procedure	7.3.1-7.3.9, 8.2.1	820.30
SOP 7-006	Supplier Management Procedure	7.4.1, 7.5.1	820.50
SOP 7-009	Calibration System Procedure	7.6	820.72
SOP 7-012	Process Validation Procedure	7.5.6	820.75
SOP 7-014	Installation Qualification Procedure	7.5.1, 7.5.6	820.70
SOP 7-015	Protocols and Reports Procedure	7.5.6	820.75
SOP 7-017	First Article Inspection Procedure	7.4.3	820.80
SOP 7-021	Design Transfer Procedure	7.3.8	820.30
SOP 7-022	Design Change Procedure	7.3.9	820.30
SOP 7-026	Product Stability (Shelf Life) Procedure	7.3	820.30
SOP 7-027	Labeling Review and Approval Procedure	7.3	820.120
SOP 7-028	Product Performance Specifications	7.3	820.30
SOP 7-029	Design Verification and Validation Procedure	7.3.7	820.30
SOP 7-030	Design Risk Management Procedure	7.3, 8.2.1	820.30
SOP 7-031	Process Risk Management Procedure	7.3, 8.2.1	820.30
SOP 7-032	Design Analysis Procedure	7.3, 8.2.1	820.30
SOP 7-033	Software Validation Procedure	7.5.6	820.75
SOP 7-034	Biocompatibility and Toxicity Testing Procedure	7.3, 7.5.1, 7.5.2	820.75

7.0 Product Realization

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QSR*
SOP 7-037	Unique Device Identification (UDI) Procedure	7.3.3	820.120
SOP 7-038	Clinical Evaluations Procedure	MDR, 8.2, 8.2.3	820.30
SOP 7-039	Clinical Investigation Procedure	MDR, 8.2,8.2.3	820.30
SOP 7-040	CE Marking Procedure	4.2.3, 7.3.10	-
SOP 7-041	Injection Mold Validation Procedure	7.5.6	820.75
SOP 7-042	Human Factors and Usability Engineering Procedure	7.3.1-7.3.8	820.30
SOP 7-043	Software as a Medical Device Development Procedure	7.3.1-7.3.8	820.30
SOP 7-044	Software Clinical Evaluation Procedure	7.3.1-7.3.8	820.30
SOP 7-046	Customer Requirements Validation Procedure	7.3.1-7.3.8	820.30

8.0 Measurement, Analysis And Improvement

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QSR*
SOP 8-001	Complaint Handling Procedure	8.2.1, 8.2.2, 8.2.3	820.198
SOP 8-002	Complaint Trending Procedure	8.2.1, 8.2.2, 8.2.3	820.198
SOP 8-004	Corrective and Preventive Action System	8.5.2, 8.5.3	820.100
SOP 8-007	Statistical Techniques Procedure	8.4	820.250
SOP 8-014	Failure Investigation Procedure	8.2.1, 8.2.2, 8.2.3	820.198

* Regulatory citations are reproduced from the source content list. These references have not been updated as part of this design revision.