DESIGN

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.

26 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	-
SOP 4-001	Engineering Change Notice (ECN) Procedure	4.2.4	820.40
SOP 4-002	Document Control Procedure	4.2.4	820.40

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

6.0 Resource Management

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QSR*
SOP 6-001	Training & Job description Procedure	6.1, 6.2	820.25

7.0 Product Realization

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QSR*
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

7.0 Product Realization

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QSR*
SOP 7-003	Risk Management Procedure	7.3.1-7.3.9, 8.2.1	820.30
SOP 7-012	Process Validation Procedure	7.5.6	820.75
SOP 7-015	Protocols and Reports Procedure	7.5.6	820.75
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 7-034	Biocompatibility and Toxicity Testing Procedure	7.3, 7.5.1, 7.5.2	820.75
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 7-042	Human Factors and Usability Engineering Procedure	7.3.1-7.3.8	820.30
SOP 7-046	Customer Requirements Validation	7.3.1-7.3.8	820.30

8.0 Measurement, Analysis And Improvement

DOCUMENT ID	DOCUMENT TITLE	ISO 13485	QSR*
SOP 8-007	Statistical Techniques Procedure	8.4	820.250

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