ISO 13485:2016 Mapping of Requirements to Documents

This table maps all requirements of the ISO 13485:2016 (by section) to the relevant documents.

> Note that the document names in the "Fulfilled in Document" column are based on the OpenRegulatory templates. You'll probably have a different system for assigning document names, so feel free to rename them.

ISO 13485:2016

Section	Title	Document
4.1	General QMS Requirements	*Quality Management ManualSOP Management ReviewSOP PurchasingSOP Software Validation*
4.2.1	General Documentation Requirements	*Quality Management Manual*
4.2.2	Quality Management Manual	*Quality Management Manual*
4.2.3	Medical Device File	*SOP Product Certification and RegistrationSOP Integrated Software Development*
4.2.4	Control of Documents	*SOP Document and Record Control*
4.2.5	Control of Records	*SOP Document and Record Control*
5.1	Management Obligations	*Quality Management ManualTemplate Annual Strategic GoalsSOP Management Review*
5.2	Client Orientation	*SOP Update of RegulationsTemplate Annual Strategic Goals*
5.3	Quality Policies	*Quality Management ManualTemplate Annual Strategic GoalsSOP Management Review*
5.4	QMS Planning and Quality Goals	*Quality Management ManualTemplate Annual Strategic GoalsSOP Management Review*
5.5	Responsibilities, Competencies and Communication	*Quality Management Manual*
5.6	Management Review	*SOP Management Review*
6.1	Allocation of Resources	*Template Annual Strategic GoalsSOP Management Review*
6.2	Staff Resources	*SOP Human Resources Administration*
6.3	Infrastructure	*SOP Software Validation*
6.4	Work Environment	*- not applicable -*

Section	Title	Document
6.4.2	Control of Contamination	*- not applicable -*
7.1	Planning of Product Development	*SOP Integrated Software Development*
7.2	Customer-Oriented Processes	*SOP Integrated Software DevelopmentSOP Feedback Management*
7.3	Development	*SOP Integrated Software DevelopmentSOP Product Certification and RegistrationSOP Change Management*
7.4	Purchasing	*SOP Purchasing*
7.5	Production and Service Provision	*SOP Integrated Software Development*
7.5.5	Special Requirements for Sterile Medical Devices	*- not applicable -*
7.5.9	Traceability	*SOP Product Certification and Registration*
7.6	Control of Surveillance and Measurement	*SOP Post-Market SurveillanceSOP Computerized Software Validation*
8.1	General Measurement, Analysis and Improvement	*SOP Integrated Software DevelopmentSOP Internal AuditingSOP Management Review*
8.2.1	Feedback	*SOP Feedback Management*
8.2.2	Complaint Processing	*SOP Feedback ManagementSOP Corrective and Preventive Actions*
8.2.3	Reporting to Authorities	*SOP Incident Reporting*
8.2.4	Internal Audit	*SOP Internal Auditing*
8.2.5	Surveillance and Measurement of Processes	*SOP Management Review*
8.2.6	Surveillance and Measurement of Products	*SOP Post-Market Surveillance*
8.3	Control of Nonconforming Products	*SOP Corrective and Preventive ActionsSOP Incident Reporting*
8.4	8.4 Data Analysis	*SOP Management Review*
8.5	8.5 Improvement: Corrective and Preventive Action	*SOP Corrective and Preventive Actions*