13485Store		13485Store		13485Store	
ISO 13485:2016 - Medical Devices		**Doc #**	**Document / Procedure Name**	**FDA**	**FDA.QSR (21 CFR 820)**
Clause	Quality Management Systems - Requirements for Regulatory Purposes			Clause	
1	Scope			820.1	Scope
2	Normative references				
3	Terms and definitions			820.3	Definitions
4	Quality Management System	QMD-002	Manual	820.5	Quality system
4.1	General requirements				
4.1.1	Document a QMS …				
4.1.2	Determine the processes …				
4.1.3	For each QMS process …				
4.1.4	Processes evaluated for impacts …				
4.1.5	Outsourced processes controlled …				
4.1.6	Computer software validated …				
4.2	Documentation requirements				
4.2.1	General				
4.2.2	Quality manual	QMD-002	Quality Manual		
4.2.3	Medical device file				
4.2.4	Control of documents	P-424	Document control	820.40	Document controls
4.2.5	Control of records	P-425	Control of quality records	820.181	Device master record
				820.184	Device history record
				820.186	Quality system record
5	Management Responsibility			820.20	Management Responsibility
5.1	Management commitment	P-500	Management responsibility		
5.2	Customer focus				
5.3	Quality policy				
5.4	Planning				
5.4.1	Quality objectives				
5.4.2	Quality management system planning				
5.5	Responsibility, authority and communication				
5.5.1	Responsibility and authority				
5.5.2	Management representative				
5.5.3	Internal communication				
5.6	Management review			820.20 c	Management review
5.6.1	General				
5.6.2	Review input				
5.6.3	Review output				
6	Resource Management				
6.1	Provision of resources			820.20 b2	Resources
6.2	Human Resources	P-620	Competence, awareness and training	820.250	Personnel
6.3	Infrastructure	P-630	Infrastructure	820.70 f	Buildings
6.4	Work environment and contamination control	P-640	Work environment and contamination control	820.70 c	Environmental controls
6.4.1	Work environment				
6.4.2	Contamination control			820.70 e	Contamination control
7	Product Realization				
7.1	Planning of product realization	P-710	Planning of product realization processes	820.30 j	Design history file
7.2	Customer related processes	P-720	Customer related processes		
7.2.1	Determination of requirements related to product	P-722	Risk management		
7.2.2	Review of requirements related to product				
7.2.3	Communication				
7.3	Design and development	P-730	Design and development	820.300	Design controls
7.3.1	General				
7.3.2	Design and development planning				
7.3.3	Design and development inputs				
7.3.4	Design and development outputs				
7.3.5	Design and development review				
7.3.6	Design of development verification				
7.3.7	Design of development validation				
7.3.8	Design and development transfer				
7.3.9	Control of design and development changes				
7.3.10	Design and development files			820.30 j	Design history file
7.4	Purchasing	P-740	Purchasing	820.500	Purchasing controls
7.4.1	Purchasing process				
7.4.2	Purchasing information				
7.4.3	Verification of purchased product				
7.5	Production and service provision	P-750	Control of production and service provision		
7.5.1	Control of production and service provision				
7.5.2	Cleanliness of product			820.70 e	Contamination control
7.5.3	Installation activities			820.170	Installation
7.5.4	Servicing activities			820.200	Servicing
7.5.5	Particular requirements for sterile medical devices	P-751	Production and process controls	820.700	Production and process controls
7.5.6	Validation of processes for production and service provision	P-756	Validation of processes for product and service provision	820.750	Process validation
7.5.7	Particular requirements for validation of processes for sterilization and sterile barrier systems				
7.5.8	Identification	P-758	Identification and traceability	820.600	Identification
7.5.9	Traceability			820.650	Traceability
7.5.9	Traceability			820.860	Acceptance status
				820.120	Labelling
7.5.9.1	General				
7.5.9.2	Particular requirements for implantable medical devices				
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				820.140	Handling
				820.150	Storage
				820.160	Distribution
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8	Measurement, Analysis, and Improvement				
8.1	General				
8.2	Monitoring and measurement				
8.2.1	Feedback	P-820	Post production feedback		
8.2.2	Complaint handling			820.198	Complaint files
8.2.3	Reporting to regulatory authorities			820.198	Complaint files
8.2.4	Internal audit	P-824	Internal audit	820.220	Quality audit
8.2.5	Monitoring and measurement of processes				
8.2.6	Monitoring and measurement of product	P-826	Monitoring, measuring and analysis of products and processes	820.800	Receiving, in-process, and finished device acceptance
8.3	Control of nonconforming product	P-830	Control of nonconforming product	820.900	Nonconforming product
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8.3.2	Actions in response to nonconforming product detected before delivery				
8.3.3	Actions in response to nonconforming product detected after delivery	P-833	Advisory notices and product recall	820.198 d	Reporting to FDA
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