FDA-QSR-21CFR-820	ISO 13485
§ 820.1 - Scope.	1 Scope 2 Normative References
§ 820.3 - Definitions.	3 Terms and Definitions
§ 820.5 - Quality system.	4 Quality Management System 4.1 General Requirements 4.2 Documentation Requirements
Subpart B--Quality System Requirements	
§ 820.20 - Management responsibility.	5.0 Management Responsibility
§ 820.22 - Quality audit.	8.2.4 Internal Quality Audits
§ 820.25 - Personnel.	6 Resource Management
Subpart C--Design Controls	
§ 820.30 - Design controls.	7.1 Planning of Product Realization 7.2.1 Customer Related Processes 7.2.2 Review of Requirements Related to Product 7.3 Design and Development
Subpart D--Document Controls	
§ 820.40 - Document controls.	4.2.4 Control of Documents
Subpart E--Purchasing Controls	
§ 820.50 - Purchasing controls.	7.4.1 Purchasing Process 7.4.2 Purchasing Information 7.4.3 Verification of Purchased Product
Subpart F--Identification and Traceability	
§ 820.60 - Identification.	7.5.8 Identification
§ 820.65 - Traceability.	7.5.9 Traceability
Subpart G--Production and Process Controls	

§ 820.70 - Production and process controls.	6.2 Human Resources 6.3 Infrastructure 6.4 Work Environment and Contamination Control 7.5.1 Control of Production and Service Provision 7.5.6 Validation of Processes for Production and Service Provision
§ 820.72 - Inspection, measuring, and test equipment.	7.6 Control of Monitoring and Measurement Equipment
§ 820.75 - Process validation.	7.5.6 Validation of Production and Service Provision
Subpart H--Acceptance Activities	
§ 820.80 - Receiving, in-process, and finished device acceptance.	7.1 Planning of Product Realization 7.4.3 Verification of Purchased Product 7.5.1 Control of Production and Service Provision
§ 820.86 - Acceptance status.	7.5.8 Identification
Subpart I--Nonconforming Product	
§ 820.90 - Nonconforming product.	8.3 Control of Nonconforming Product
Subpart J--Corrective and Preventive Action	
§ 820.100 - Corrective and preventive action.	8.5.2 Corrective Action 8.5.3 Preventative Action
Subpart K--Labeling and Packaging Control	
§ 820.120 - Device labeling.	4.2.3 Medical Device File 7.5.8 Identification 7.5.11 Preservation of Product
§ 820.130 - Device packaging.	4.2.3 Medical Device File 7.5.8 Identification 7.5.11 Preservation of Product
Subpart L--Handling, Storage, Distribution, and Installation	

§ 820.140 - Handling.	4.2.3 Medical Device File 7.1 Planning of Product Realization 7.5.8 Identification 7.5.11 Preservation of Product
§ 820.150 - Storage.	4.2.3 Medical Device File 7.1 Planning of Product Realization 7.5.8 Identification 7.5.11 Preservation of Product
§ 820.160 - Distribution.	4.2.3 Medical Device File 7.1 Planning of Product Realization 7.5.8 Identification 7.5.11 Preservation of Product
§ 820.170 - Installation.	4.2.3 Medical Device File 7.5.3 Installation Activities 7.5.8 Identification 7.5.11 Preservation of Product
Subpart M--Records	
§ 820.180 - General requirements.	4.2 Documentation Requirements 4.2.3 Medical Device File 7.1 Planning of Product Realization
§ 820.181 - Device master record.	4.2.3 Medical Device File
§ 820.184 - Device history record.	4.2.5 Control Records 7.1 Planning of Product Realization 7.5.8 Identification
§ 820.186 - Quality system record.	4.2 Documentation Requirements 7.1 Planning of Product Realization
§ 820.198 - Complaint files.	7.2.3 Communication 8.2.1 Feedback 8.2.2 Complaint Handling 8.2.3 Reporting to Regulatory Authorities
Subpart N--Servicing	

§ 820.200 - Servicing.	4.2.3 Medical Device File 7.1 Planning of Product Realization 7.5.4 Servicing 7.5.8 Identification
Subpart O--Statistical Techniques	
§ 820.250 - Statistical techniques.	8.1 General 8.4 Analysis of Data