WINOVIA
Quality Management Systems Consulting

21 CFR Part 820 and ISO13485:2016 Comparison Matrix

21 CFR Part 820	ISO 13485:2016
§820.1 Scope and Applicability	1 Scope
§820.3 Definitions	3 Terms and Definitions
§820.5 Quality System	4.1.1 Quality Management System General Requirements 4.2.2 Quality Manual
§820.20 Management Responsibility	5 Management Responsibility 5.2 Customer Focus 5.5 Responsibility and Authority
§820.20 (a) Quality Policy	5.3 Quality Policy
§820.20 (b) Organization	4.1 Quality Management Systems - General Requirements 5.5.1 Responsibility and Authority
§820.20 (b)(2) Resources	6.1 Provision of Resources 6.2 Human Resources
§820.20 (b)(3) Management Representative	5.5.2 Management Representative
§820.20 (c) Management Review	5.6 Management Review
§820.20 (d) Quality Planning	5.4 Planning
§820.20 (e) Quality System Procedures	4.2.2 (b) Quality Manual
§820.22 Quality Audit	8.2.4 Internal Audit
§820.25 Personnel	6 Resource Management
§820.25 (a) General	6.1 Provision of Resources
§820.25 (b) Training	6.2 Human Resources
§820.30 Design Controls	7.3 Design and Development
§820.30 (a) General	7.3.1 General
§820.30 (b) Design and Development Planning	7.1 Planning of Product Realization 7.3.2 Design and Development Planning
§820.30 (c) Design Input	7.2 Customer Related Processes 7.3.3 Design and Development Inputs
§820.30 (d) Design Output	7.3.4 Design and Development Output
§820.30 (e) Design Review	7.3.5 Design and Development Review
§820.30 (f) Design Verification	7.3.6 Design and Development Verification
§820.30 (g) Design Validation Risk Analysis	7.3.7 Design and Development Validation 7.1 Planning of Product Realization (risk management)
§820.30 (h) Design Transfer	7.3.8 Design and Development Transfer
§820.30 (i) Design Changes	7.3.9 Control of Design and Development Changes
§820.30 (j) Design History File	7.3.10 Design and Development Files
§820.40 Document Controls	4.2.4 Control of Documents
§820.40 (a) Document Approval and Distribution	4.2.4 Control of Documents

21 CFR Part 820 and ISO13485:2016 Comparison Matrix

21 CFR Part 820	ISO 13485:2016
§820.40 (b) Document Changes	4.2.4 Control of Documents
§820.50 Purchasing Controls	7.4 Purchasing
§820.50 (a) Evaluation of Suppliers	7.4.1 Purchasing Process
§820.50 (b) Purchasing Data	7.4.2 Purchasing Information 7.4.3 Verification of Purchased Product
§820.60 Identification	7.5.8 Identification
§820.65 Traceability	7.5.9 Traceability
§820.70 Production and Process Controls	7.5 Production and Service Provision
§820.70 (a) General	7.5.1 Control of Production and Service Provision
§820.70 (b) Production and Process Changes	7.5.6 (g) Validation of Processes for Production and Service Provisions 7.5.7 Particular requirements for Validation of Processes for Sterilization and Sterile Barrier Systems
§820.70 (c) Environmental Control	6.4 Work Environment and Contamination Control 6.4.1 Work environment
§820.70 (d) Personnel	6.4 Work Environment and Contamination Control 6.4.1 Work environment
§820.70 (e) Contamination Control	6.4 Work Environment and Contamination Control 6.4.2 Contamination Control 7.5.2 Cleanliness of product
§820.70 (f) Buildings	6.3 Infrastructure
§820.70 (g) Equipment	6.3 Infrastructure 7.5.1 (b) Control of Production and Service Provision 7.5.6 (b) Validation of Processes for Production and Service Provision
§820.70 (h) Manufacturing Material	7.5.2 (e) Cleanliness of Product
§820.70 (i) Automated Processes	4.1.6 Quality Management System General Requirements 7.5.6 Validation of Processes for Production and Service Provisions 7.6 Control of Monitoring and Measuring Devices
§820.72 Inspection, Measuring and Test Equipment	7.6 Control of Monitoring and Measuring Devices
§820.72 (a) Control of inspection, measuring and test equipment	7.6 Control of Monitoring and Measuring Devices
§820.72 (b) Calibration	7.6 Control of Monitoring and Measuring Devices
§820.75 Process Validation	7.5.6 Validation of Processes for Production and Service Provisions 7.5.7 Particular requirements for Validation of Processes for Sterilization and Sterile Barrier Systems
§820.80 Acceptance Activities	7.1 (c) Planning of Product Realization 8.2.6 Monitoring and Measuring of Product
§820.80 (a) General	7.1 (c) Planning of Product Realization 8.2.6 Monitoring and Measuring of Product
§820.80 (b) Receiving Acceptance Activities	7.1 (c) Planning of Product Realization 8.2.6 Monitoring and Measuring of Product

21 CFR Part 820 and ISO13485:2016 Comparison Matrix

21 CFR Part 820	ISO 13485:2016
§820.80 (c) In-process Acceptance Activities	7.1 (c) Planning of Product Realization 8.2.6 Monitoring and Measuring of Product
§820.80 (d) Final Acceptance Activities	7.1 (c) Planning of Product Realization 8.2.6 Monitoring and Measuring of Product
§820.80 (e) Acceptance Records	4.2.5 Control of Records 7.1 (c) Planning of Product Realization 8.2.6 Monitoring and Measuring of Product
§820.86 Acceptance Status	7.5.8 Identification
§820.90 Nonconforming Product	8.3 Control of Nonconforming Product
§820.90 (a) Control of Nonconforming Product	8.3.1 General
§820.90 (b) Nonconformity Review and Disposition	8.3.2 Actions in Response to Non-conforming Product Detected Before Delivery 8.3.3 Actions in Response to Non-conforming Product Detected After Delivery 8.3.4 Rework
§820.100 Corrective and Preventive Action	8.4 Analysis of Data 8.2.5 Monitoring and Measurement of Processes 8.5 Improvement 8.5.1 General 8.5.2 Corrective Action 8.5.3 Preventive Action
§820.120 Device Labeling	7.5.1 (e) Control of Production and Service Provisions
§820.120 (a) Label Integrity	7.5.1 (e) Control of Production and Service Provisions
§820.120 (b) Labeling Inspection	7.5.1 (e) Control of Production and Service Provisions
§820.120 (c) Labeling Storage	7.5.1 (e) Control of Production and Service Provisions
§820.120 (d) Labeling Operations	7.5.1 (e) Control of Production and Service Provisions
§820.120 (e) Control Number	7.5.8 Identification (Unique Device Identification)
§820.130 Device Packaging	7.5.1 (e) Control of Production and Service Provisions 7.5.11 (a) Preservation of Product
§820.140 Handling	7.5.10 Customer Property 7.5.11 Preservation of Product
§820.150 Storage	7.5.10 Customer Property 7.5.11 Preservation of Product
§820.160 Distribution	7.5.1 Control of Production and Service Provisions (last paragraph) 7.5.10 Customer Property 7.5.11 Preservation of Product
§820.170 Installation	7.5.3 Installation Activities
§820.180 Records	4.2.5 Control of Records
§820.180 (a) Confidentiality	4.2.5 Control of Records
§820.180 (b) Record Retention Period	4.2.4 Control of Documents 4.2.5 Control of Records
§820.180 (c) Exceptions	Not specified (All records can be audited)
§820.181 Device Master Record	4.2.3 Medical Device File

21 CFR Part 820 and ISO13485:2016 Comparison Matrix

21 CFR Part 820	ISO 13485:2016
§820.184 Device History Record	7.5.1 Last Paragraph 7.5.5 Particular requirements for Sterile Medical Devices
§820.186 Quality System Record	4.2.5 Control of Records (does not specify the term quality system record)
§820.198 Complaint Files	8.2.2 Complaint Handling 8.2.3 Reporting to Regulatory Authorities
§820.200 Servicing	7.5.4 Servicing Activities 8.4 (f) Analysis of Data
§820.250 Statistical Techniques	7.3.6 Design and Development Verification 7.3.7 Design and Development Validation 7.5.6 Validation of Processes for Production and Service Provision 8.1 Measurement Analysis and Improvement - General 8.4 Analysis of Data