WINOVIA
Quality Management Systems Consulting

ISO13485:2016 and 21 CFR Part 820 Comparison Matrix

ISO 13485:2016	21 CFR Part 820
0 Introduction	No corresponding section (Preamble to 21 CFR Part 820)
1 Scope	§820.1 Scope and Applicability
2 Normative References	No corresponding section
3 Terms and Definitions	§820.3 Definitions
4 Quality Management Systems	§820.5 Quality System
4.1 General Requirements	§820.5 Quality System
4.1.6 General requirements	§820.70 (i) Automated processes
4.2 Documentation requirements	§820.40 Document Controls
4.2.1 General	§820.40 Document Controls
4.2.2 Quality manual	No specific requirement for a Quality Manual §820.5 Quality System §820.186 Quality System Record
4.2.3 Medical device file	§820.181 Device Master Record (DMR)
4.2.4 Control of documents	§820.40 Document Controls §820.180 Records – General Requirements`
4.2.5 Control of records	§820.180 Records – General Requirements §820.80 (e) Acceptance Records
5 Management Responsibility	§820.20 Management Responsibility
5.1 General	§820.20 Management Responsibility (a) Quality Policy
5.2 Customer focus	No specific requirement for customer focus
5.3 Quality Policy	§820.20 (a) Management Responsibility - Quality Policy
5.4 Planning	§820.20 (d) Management Responsibility - Quality Planning
5.4.1 Quality objectives	No specific requirement of quality objectives
5.4.2 Quality management system planning	§820.20 (d) Management Responsibility - Quality Planning
5.5 Responsibility, Authority and Communication	§820.20 Management Responsibility
5.5.1 Responsibility and authority	§820.20 (b) (1) Management Responsibility - Responsibility and authority
5.5.2 Management representative	§820.20 (b) (3) Management Responsibility - Management Representative
5.5.3 Internal communication	No specific requirement for internal communication
5.6 Management Review	§820.20 (c) Management Responsibility - Management Review §820.100 (a) (7) Corrective and Preventive Action
6 Resource Management	§820.20 (b) (2) Management Responsibility - Resources §820.25 Personnel
6.1 Provision of resources	§820.20 (b) (2) Management Responsibility - Resources
6.2 Human resources	§820.25 Personnel
6.3 Infrastructure	§820.70 (f) Production and Process Controls - Buildings §820.70 (g) Production and Process Controls - Equipment

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6.4 Work environment and contamination control	§820.70 (c) Production and Process Controls - Environmental Control §820.70 (d) Production and Process Controls - Personnel §820.70 (e) Production and Process Controls - Contamination Control
6.4.1 Work environment	§820.70 (c) Production and Process Controls - Environmental Control §820.70 (d) Production and Process Controls - Personnel
6.4.2 Contamination control	§820.70 (e) Production and Process Controls - Contamination Control
7 Product Realization	§820.30 (g) Design Validation - Risk Analysis
7.1 Panning of product realization	No specific requirement for product realization
7.2 Customer related processes	No specific requirement for customer related processes
7.2.1 Determination of requirements related to product	No specific requirement §820.30 (c) Design Input
7.2.2 Review of requirements related to product	No specific requirement §820.30 (e) Design Review
7.2.3 Communication	No specific requirement
7.3 Design and Development	§820.30 Design Controls
7.3.1 General	§820.30 (a) General
7.3.2 Design and Development Planning	§820.30 (b) Design and Development Planning
7.3.3 Design and Development inputs	§820.30 (c) Design Input
7.3.4 Design and Development outputs	§820.30 (d) Design Output
7.3.5 Design and Development review	§820.30 (e) Design Review
7.3.6 Design and Development verification	§820.30 (f) Design Verification §820.250 Statistical techniques
7.3.7 Design and Development validation	§820.30 (g) Design Validation §820.250 Statistical techniques
7.3.8 Design and Development transfer	§820.30 (h) Design Transfer
7.3.9 Control of Design and Development changes	§820.30 (i) Design Changes
7.3.10 Design and Development files	§820.30 (j) Design History File
7.4 Purchasing	§820.50 Purchasing Controls
7.4.1 Purchasing process	§820.50 (a) Purchasing Controls - Evaluation of suppliers, contractors and consultants
7.4.2 Purchasing information	§820.50 (b) Purchasing Controls - Purchasing data
7.4.3 Verification of purchased product	§820.50 (b) Purchasing Controls - Purchasing data
7.5 Production and Service Provision	§820.70 Production and Process Controls §820.170 Installation §820.200 Servicing
7.5.1 Control of production and service provision	§820.70 (a) Production and Process Controls - General
7.5.1 (b) Qualification of infrastructure	§820.70 (g) Production and Process Controls - Equipment

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7.5.1 (d) Availability of monitoring and measuring equipment	§820.72 Inspection, measuring, and test and equipment
7.5.1 (e) Defined operations for labeling and packaging	§820.120 Device Labeling §820.130 Device Packaging
7.5.1 (f) Product release, delivery and post-delivery activities	§820.80 Receiving, in-process, and finished device acceptance §820.70 (b) Production and Process Controls - Production and Process Changes §820.170 Installation §820.200 Servicing
7.5.1 Last paragraph – Establish and maintain a record of each medical device or batch of medical devices…	§820.184 Device History Record
7.5.2 Cleanliness of product	§820.70 (e) Production and Process Controls - Contamination of product §820.70 (h) Production and Process Controls - Manufacturing material
7.5.3 Installation activities	§820.170 Installation
7.5.4 Servicing activities	§820.200 Servicing
7.5.5 Particular requirement for sterile medical devices	No specific requirement for sterile medical devices §820.75 Process Validation §820.70 (i) Automated processes
7.5.6 Validation of processes for production and service provision	§820.75 Process Validation §820.70 (i) Automated processes
7.5.6 (b) Equipment qualification / qualification of personnel	§820.70 (g) Production and Process Controls - Equipment
7.5.6 (c) Acceptance criteria	§820.80 Receiving, in-process, and finished device acceptance
7.5.6 (d) Statistical techniques	§820.250 Statistical techniques
7.5.6 (f) Revalidation	§820.70 (b) Production and Process Controls - Production and Process Changes §820.75 (c) Process Validation
7.5.6 (g) Changes to the process	§820.70 (b) Production and Process Controls - Production and Process Changes §820.75 (c) Process Validation
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems	No specific requirement for sterile barrier systems §820.75 Process Validation §820.70 (i) Automated processes
7.5.8 Identification	§820.60 Identification §820.86 Acceptance status
7.5.9 Traceability	No specific requirement for general traceability
7.5.9.2 Particular requirements for implantable medical devices	§820.65 Traceability
7.5.10 Customer property	No specific requirement for customer property §820.140 Handling

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	§820.150 Storage §820.160 Distribution
7.5.11 Preservation of product	§820.130 Device Packaging §820.140 Handling §820.150 Storage §820.160 Distribution
7.6 Control of monitoring and measuring equipment	§820.72 Inspection, measuring, and test and equipment §820.70 (i) Automated processes
8 Measurement, Analysis and Improvement	§820.100 (a) Corrective and Preventive Action §820.250 Statistical techniques
8.1 General	§820.100 Corrective and Preventive Action §820.250 Statistical techniques
8.2 Monitoring and measurement	No specific requirement for monitoring and measurement §820.100 (a) Corrective and Preventive Action
8.2.1 Feedback	
8.2.2 Complaint Handling	§820.198 Complaint Files
8.2.3 Reporting to Regulatory Authorities	§820.198 (d) Complaint Files Covered by 21 CFR Part 803 Medical Device Reporting
8.2.4 Internal Audit	§820.22 Quality Audit
8.2.5 Monitoring and measurement of processes	§820.100 (a) Corrective and Preventive Action
8.2.6 Monitoring and measurement of product	§820.80 Receiving, in-process, and finished device acceptance
8.3 Control of nonconforming product	§820.90 Nonconforming product
8.3.1 General	§820.90 (a) Nonconforming product – Control of nonconforming product
8.3.2 Actions in response to nonconforming product detected before delivery	§820.90 (b) (1) Nonconforming product – Nonconformity review and disposition
8.3.3 Actions in response to nonconforming product detected after delivery	No specific requirement for monitoring and measurement §820.198 Complaint Files Covered by 21 CFR Part 806 Corrections and Removals
8.3.4 Rework	§820.90 (b) (2) Nonconforming product – Nonconformity review and disposition
8.4 Analysis of data	§820.100 (a) Corrective and Preventive Action §820.250 Statistical techniques §820.200 (b) Servicing
8.5 Improvement	§820.100 Corrective and Preventive Action
8.5.1 General	§820.100 Corrective and Preventive Action
8.5.2 Corrective action	§820.100 Corrective and Preventive Action
8.5.3 Preventive action	§820.100 Corrective and Preventive Action