| **ISO 13485:2016** (Medical devices – Quality management systems – Requirements for regulatory purposes) | **USA 21 CFR Part 820** (FDA Quality System Regulation) |
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| 4 Quality management system  4.1 General requirements | 820.5 Quality system |
| 4.2 Documentation requirements  4.2.1 General | 820.5 Quality system |
| 4.2.2 Quality manual |  |
| 4.2.3 Medical device file  4.2.4 Control of documents  4.2.5 Control of records | 820.40 Document controls  820.180 General requirements  820.181 Device master record  820.184 Device history record  820.186 Quality system record |
| 5 Management responsibility  5.1 Management commitment | 820.20 Management responsibility |
| 5.2 Customer focus |  |
| 5.3 Quality policy | 820.20 Management responsibility  (a) Quality policy |
| 5.4 Planning  5.4.1 Quality objectives | 820.20 Management responsibility  (a) Quality policy |
| 5.4.2 Quality management system planning | 820.5 Quality system  (d) Quality planning  (e) Quality system procedures |
| 5.5 Responsibility, authority and communication  5.5.1 Responsibility and authority | 820.20 Management responsibility  (b) Organization (1) Responsibility and authority |
| 5.5.2 Management representative | 820.20 Management responsibility  (a) Organization (3) Management representative |
| 5.5.3 Internal communication | 820.20 Management responsibility (b) Organization |
| 5.6 Management review  5.6.1 General  5.6.2 Review input  5.6.3 Review output | 820.20 Management responsibility  (c) Management review |
| 6. Resource management  6.1 Provision of resources | 820.20 Management responsibility  (b) Organization (2) Resources |
| 6.2 Human resources | 820.20 Management responsibility  (b) Organization (2) Resources  820.25 Personnel  (a) General  (b) Training |
| 6.3 Infrastructure | 820.70 Production and process control  (f) Buildings  (g) Equipment (1) Maintenance schedule, (2) Inspection,  (3) Adjustment |
| 6.4 Work environment and contamination control  6.4.1 Work environment  6.4.2 Contamination control | 820.70 Production and process controls  (c) Environmental control  (d) Personnel  (e) Contamination control |
| 7 Product realization  7.1 Planning of product realization | 820.5 Quality system |
| 7.2 Customer-related processes  7.2.1 Determination of requirements related to the product  7.2.2 Review of requirements related to the product  7.2.3 Communication |  |
| 7.3 Design and development  7.3.1 General  7.3.2 Design and development planning | 820.30 Design controls  (a) General  (b) Design and development planning |
| 7.3.3 Design and development inputs | 820.30 Design controls (c) Design input |
| 7.3.4 Design and development outputs | 820.30 Design controls (d) Design output |
| 7.3.5 Design and development review | 820.30 Design controls (e) Design review |
| 7.3.6 Design and development verification | 820.30 Design controls (f) Design verification |
| 7.3.7 Design and development validation | 820.30 Design controls (g) Design validation |
| 7.3.8 Design and development transfer | 820.30 Design controls (h) Design transfer |
| 7.3.9 Control of design and development changes | 820.30 Design controls (i) Design changes |
| 7.3.10 Design and development files | 820.30 Design controls (j) Design history file |
| 7.4 Purchasing  7.4.1 Purchasing process | 820.50 Purchasing controls.  (a) Evaluation of suppliers, contractors, and consultants |
| 7.4.2 Purchasing information | 820.50 Purchasing controls (b) Purchasing data |
| 7.4.3 Verification of purchased product | 820.80 Receiving, in-process, and finished device acceptance  (b) Receiving acceptance activities  (e) Acceptance records  820.86 Acceptance status |
| 7.5 Production and service provision  7.5.1 Control of production and service provision | 820.70 Production and process controls  (a) General  (b) Production and process changes  (h) Manufacturing material  820.120 Device labeling  (a) Label integrity  (b) Labeling inspection  (c) Labeling storage  (d) Labeling operations  (e) Control number  820.184 Device history record |
| 7.5.2 Cleanliness of product | 820.70 Production and process controls  (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 | Not applicable |
| 7.5.6 Validation of processes for production and service provision | 820.70 Production and process controls  (i) Automated processes  820.75 Process validation |
| 7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems | Not applicable |
| 7.5.8 Identification  7.5.9 Traceability  7.5.9.1 General  7.5.9.2 Particular requirements for implantable medical devices | 820.60 Identification  820.65 Traceability  820.80 Receiving, in-process, and finished device acceptance  (e) Acceptance records  820.86 Acceptance status |
| 7.5.10 Customer property | Not applicable |
| 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 equipment  (a) Control of inspection, measuring, and test equipment  (b) Calibration (1) Calibration standards (2) Calibration records |
| 8 Measurement, analysis and improvement  8.1 General | 820.250 Statistical techniques |
| 8.2 Monitoring and measurement  8.2.1 Feedback | 820.198 Complaint files (803) |
| 8.2.2 Complaint handling | 820.198 Complaint files (803) |
| 8.2.3 Reporting to regulatory authorities | 820.198 Complaint files (803) |
| 8.2.4 Internal audit | 820.22 Quality audit |
| 8.2.5 Monitoring and measurement of processes | 820.70 Production and process controls  (a) General |
| 8.2.6 Monitoring and measurement of product | 820.80 Receiving, in-process, and finished device acceptance  (a) General  (b) Receiving acceptance activities  (c) In-process acceptance activities  (d) Final acceptance activities  (e) Acceptance records  820.250 Statistical techniques |
| 8.3 Control of nonconforming product  8.3.1 General  8.3.2 Actions in response to nonconforming product detected before delivery  8.3.3 Actions in response to nonconforming product detected after delivery  8.3.4 Rework | 820.90 Nonconforming product.  (a) Control of nonconforming product  (b) Nonconformity review and disposition |
| 8.4 Analysis of data | 820.250 Statistical techniques |
| 8.5 Improvement  8.5.1 General | 820.20 Management responsibilities  (c) Management review |
| 8.5.2 Corrective action | 820.100 Corrective and preventive action |
| 8.5.3 Preventive action | 820.100 Corrective and preventive action |