| **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 system4.1 General requirements | 820.5 Quality system |
| 4.2 Documentation requirements4.2.1 General | 820.5 Quality system |
| 4.2.2 Quality manual |  |
| 4.2.3 Medical device file4.2.4 Control of documents4.2.5 Control of records | 820.40 Document controls820.180 General requirements820.181 Device master record820.184 Device history record820.186 Quality system record |
| 5 Management responsibility5.1 Management commitment | 820.20 Management responsibility |
| 5.2 Customer focus |  |
| 5.3 Quality policy | 820.20 Management responsibility(a) Quality policy |
| 5.4 Planning5.4.1 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 communication5.5.1 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 review5.6.1 General5.6.2 Review input5.6.3 Review output | 820.20 Management responsibility(c) Management review |
| 6. Resource management6.1 Provision of resources | 820.20 Management responsibility(b) Organization (2) Resources |
| 6.2 Human resources | 820.20 Management responsibility(b) Organization (2) Resources820.25 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 control6.4.1 Work environment6.4.2 Contamination control | 820.70 Production and process controls(c) Environmental control(d) Personnel(e) Contamination control |
| 7 Product realization7.1 Planning of product realization | 820.5 Quality system |
| 7.2 Customer-related processes7.2.1 Determination of requirements related to the product7.2.2 Review of requirements related to the product7.2.3 Communication |  |
| 7.3 Design and development7.3.1 General7.3.2 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 Purchasing7.4.1 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 records820.86 Acceptance status |
| 7.5 Production and service provision7.5.1 Control of production and service provision | 820.70 Production and process controls(a) General(b) Production and process changes(h) Manufacturing material820.120 Device labeling(a) Label integrity(b) Labeling inspection(c) Labeling storage(d) Labeling operations(e) Control number820.184 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 processes820.75 Process validation |
| 7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems | Not applicable |
| 7.5.8 Identification7.5.9 Traceability7.5.9.1 General7.5.9.2 Particular requirements for implantable medical devices | 820.60 Identification820.65 Traceability820.80 Receiving, in-process, and finished device acceptance(e) Acceptance records820.86 Acceptance status |
| 7.5.10 Customer property | Not applicable |
| 7.5.11 Preservation of product | 820.130 Device packaging820.140 Handling820.150 Storage820.160 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 improvement8.1 General | 820.250 Statistical techniques |
| 8.2 Monitoring and measurement8.2.1 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 records820.250 Statistical techniques |
| 8.3 Control of nonconforming product8.3.1 General8.3.2 Actions in response to nonconforming product detected before delivery8.3.3 Actions in response to nonconforming product detected after delivery8.3.4 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 Improvement8.5.1 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 |