

FDA 21 CFR Part 820 vs. ISO 13485:2016

Comparison Table created by greenlight.guru

| FDA QSR (21 CFR Part 820)                                       | ISO 13485:2016   |
|---|--|
| 820.1 Scope   | 1 Scope<br>2 Normative References  |
| 820.3 Definitions   | 3 Terms and Definitions  |
| 820.5 Quality System  | 4 Quality Management System<br>4.1 General Requirements<br>4.2 Documentation Requirements                                  |
| 820.20 Management Responsibility                                | 5.0 Management Responsibility  |
| 820.20(a) Quality Policy  | 5.3 Quality Policy   |
| 820.20(b) Organization  | 4.1 Management Responsibility – General  |
| 820.20(b)(1) Responsibility & Authority                         | 5.5 Responsibility & Authority   |
| 820.20(b)(2) Resources  | 5.1e Management Commitment   |
| 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 Quality Planning   |
| 820.20(e) Quality System Procedures                             | 4.2.1 General<br>4.2.2 Quality Manual  |
| 820.22 Quality Audit  | 8.2.4 Internal Quality Audits  |
| 820.25 Personnel  | 6 Resource Management  |
| 820.25(a) General   | 6.1 Provision of Resources<br>6.2 Human Resources  |
| 820.25(b) Training  | 6.2 Human Resources  |
| 820.30 Design Controls  | 7.3 Design and Development   |
| 820.30(a) General   | 7.3 Design and Development   |
| 820.30(b) Design and Development Planning                       | 7.1 Planning of Product Realization<br>7.3.2 Design and Development Planning   |
| 820.30(c) Design Input  | 7.2.1 Customer Related Processes<br>7.2.2 Review of Requirements Related to Product<br>7.3.3 Design and Development Inputs |
| 820.30(d) Design Output   | 7.3.4 Design and Development Outputs   |
| 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                                     | 7.3.7 Design and Development Validation  |
| 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   |
| 820.40(b) Document Changes                                      | 4.2.4 Control of Documents   |
| 820.50 Purchasing Controls                                      | 7.4.1 Purchasing Process   |
| 820.50(a) Evaluation of Suppliers, Contractors, and Consultants | 7.4.1 Purchasing Process   |
| 820.50(b) Purchasing Data                                       | 7.4.2 Purchasing Information<br>7.4.3 Verification of Purchased Product  |
| 820.60 Identification   | 7.5.8 Identification   |
| 820.65 Traceability   | 7.5.9 Traceability   |
| 820.70(a) Production and Process Controls                       | 7.5.1 Control of Production and Service Provision<br>7.5.6 Validation of Processes for Production and Service Provision    |

|   |   |
|---|---|
| 820.70(b) Production and Process Changes                                    | 6.3 Infrastructure<br>6.4 Work Environment and Contamination Control<br>7.5.1 Control of Production and Service Provision<br>7.5.6 Validation of Processes for Production and Service Provision |
| 820.70(c) Environmental Control   | 6.4 Work Environment and Contamination Control  |
| 820.70(d) Personnel   | 6.2 Human Resources   |
| 820.70(e) Contamination Control   | 6.4.2 Contamination Control   |
| 820.70(f) Buildings   | 6.3 Infrastructure  |
| 820.70(g) Equipment   | 6.3 Infrastructure<br>7.5.1 Control of Production and Service Provision<br>7.5.6 Validation of Production and Service Provision   |
| 820.70(h) Manufacturing Material  | 7.5.11 Preservation of Product  |
| 820.70(i) Automated Processes   | 6.3.b Infrastructure<br>7.5.6 Validation of 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  |
| 820.80(a) Receiving, In-- process, and Finished Device Acceptance – General | 7.1 Planning of Product Realization<br>7.4.3 Verification of Purchased Product<br>7.5.1 Control of Production and Service Provision   |
| 820.80(b) Receiving Acceptance  | 7.4.3 Verification of Purchased Product   |
| 820.80(c) In-- Process Acceptance   | 7.1 Planning of Product Realization   |
| 820.80(d) Final Acceptance Activities                                       | 7.1 Planning of Product Realization   |
| 820.80(e) Final Acceptance Records  | 7.1 Planning of Product Realization   |
| 820.86 Acceptance Status  | 7.5.8 Identification  |
| 820.90(a) Non-- Conforming Product  | 8.3 Control of Nonconforming Product  |
| 820.90(b) Nonconformity Review and Disposition                              | 8.3 Control of Nonconforming Product  |
| 820.100 Corrective and Preventative Action                                  | 8.5.2 Corrective Action<br>8.5.3 Preventative Action  |
| 820.120 Device Labeling   | 4.2.3 Medical Device File<br>7.5.8 Identification<br>7.5.11 Preservation of Product   |
| 820.130 Device Packaging  | 4.2.3 Medical Device File<br>7.5.8 Identification<br>7.5.11 Preservation of Product   |
| 820.140 Handling  | 4.2.3 Medical Device File<br>7.1 Planning of Product Realization<br>7.5.8 Identification<br>7.5.11 Preservation of Product  |
| 820.150 Storage   | 4.2.3 Medical Device File<br>7.1 Planning of Product Realization<br>7.5.8 Identification<br>7.5.11 Preservation of Product  |
| 820.160 Distribution  | 4.2.3 Medical Device File<br>7.1 Planning of Product Realization<br>7.5.8 Identification<br>7.5.11 Preservation of Product  |
| 820.170 Installation  | 4.2.3 Medical Device File<br>7.5.3 Installation Activities<br>7.5.8 Identification<br>7.5.11 Preservation of Product  |

|  |  |
|--|--|
| 820.180 Records  | 4.2 Documentation Requirements<br>4.2.3 Medical Device File<br>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<br>7.1 Planning of Product Realization<br>7.5.8 Identification                           |
| 820.186 Quality System Record  | 4.2 Documentation Requirements<br>7.1 Planning of Product Realization  |
| 820.198 Complaint Files  | 7.2.3 Communication<br>8.2.1 Feedback<br>8.2.2 Complaint Handling<br>8.2.3 Reporting to Regulatory Authorities |
| 820.200 Servicing  | 4.2.3 Medical Device File<br>7.1 Planning of Product Realization<br>7.5.4 Servicing<br>7.5.8 Identification    |
| 820.250 Statistical Techniques   | 8.1 General<br>8.4 Analysis of Data  |
| <p>greenlight.guru's eQMS solution is being used by some of the world's most innovative medical device companies all over the globe to help ensure their compliance to ISO 13485:2016 and FDA 21 CFR Part 820.</p> |  |
| <p>Visit <a href="http://www.greenlight.guru">www.greenlight.guru</a> to learn more about our software + services and see how we might be able to help your company.</p>   |  |