

## Appendix 5.5.3 FDA's 21Code of Federal Regulations (CFR) Part 820 Quality System Regulations<sup>1</sup>

**Interpretive Summary** – Always refer to the actual regulations for complete requirements and the most recent information. The complete regulations are available on FDA's website [www.fda.gov](http://www.fda.gov) (use keyword "21CFR Part 820" to search for them).

**Subpart A – General Provisions: Defines scope** of regulation, who must comply, FDA's authority, and the process for exemptions, import requirements. Definition section - explains FDA's meaning for key words and acronyms contained in the regulation.

**Subpart B – Quality Systems Requirements:** Management is responsible for providing the structure (policy, organization, resources, defined responsibility and authority) for a working quality system, and must be aware of the effectiveness of the current system. Awareness and corrective action is documented through periodic Management Review meetings. A quality plan outlining the structure of the system and how it is fulfilled is defined. Internal Quality Audits are performed and results shared with management. Job descriptions are generated and a sufficient number of qualified employees are trained per a predefined training plan. Persons responsible for quality are given the independence and authority to fulfill their responsibilities.

**Subpart C – Design Controls:** Class II, III and some class I devices are subject to design controls. There is a documented system for developing new products with the primary goals of proving the product to be safe and effective and that the design is both reproducible and traceable. The design is transferred to production in a way that allows production to successfully reproduce the design. The design process requirements are defined in discrete segments: input, output, review, verification (product meets design specifications), validation (that the design specifications meet customer requirements), transfer (to manufacturing), and changes (made to the design). The output of the design history process is a Design History File.

**Subpart D – Document Controls:** Document control systems are a mechanism for managing change and defining agreements on how work will be done and/or products will be produced and tested. All processes required by any part of this regulation are defined in writing and documents are reviewed and approved prior to initial release, or subsequent revision. Records of changes are maintained. Documents are revision controlled. Obsolete documents are not available for use.

**Subpart E – Purchasing:** Documented system for evaluation, approval, control, and monitoring of suppliers. Requires clear purchasing documentation be provided to suppliers. Supplier qualification begins in the design process and applies to both service and material suppliers. Known (and unavoidable) poor quality controls by a supplier translates to tighter receiving inspection criteria and vice versa.

**Subpart F – Product Identification & Traceability:** Documented system for identifying materials used in building product, and the product itself, as appropriate, in order to facilitate failure investigation and/or a recall if necessary. The level of detail required is dependent on the type of device. There are special requirements for implantable devices.

**Subpart G – Process Control:** Documented system for conducting, controlling, and monitoring production process to ensure the device conforms to its specifications. Includes instructions for processing activities; controls for equipment (preventative maintenance & Installation Qualification, Operational Qualification, Process Qualification, calibration (ensuring equipment is giving valid results), workmanship standards, manufacturing materials, environmental controls (including personnel), contamination controls, process qualification and monitoring, *validation*, automated processes (computer-controlled). Process validation is required where the results of the process cannot be fully validated by subsequent inspection and test (such as sterile products where testing would be destructive).

**Subpart H – Acceptance Activities:** Documented system for inspection and testing of incoming, in-process, and final testing. Test results are documented; devices are not released for distribution until the release is authorized in writing. Acceptance status is clearly identified throughout all stages of use so that rejected or quarantined materials are not used by mistake.

**Subpart I – Nonconforming Product:** Documented system for control of the nonconforming material or product (quarantine, label rejected, etc.) to prevent inadvertent use, and decision for what will be done with the nonconforming materials or product (rework, scrap, return to supplier, etc.). Rework requires approved and documented processing and re-inspection instructions.

**Subpart J – Corrective & Preventative Action:** Documented system for collection of information related to system, product, or material problems. Problems are investigated, the cause(s) identified, and solutions to eliminate the problems from happening again are identified and implemented (corrective action). Lastly solutions are verified as effective. Those responsible for corrective action must be made aware of the issues. Also requires that systems be in place to prevent problems from occurring before they happen (preventative action).

**Subpart K – Device Labeling and Packaging Control:** Controls for labeling activities, which are intended to prevent inadvertent mislabeling. Device packaging must protect product from alteration or damage during storage, shipping, and normal use conditions.

**Subpart L – Handling, Storage, Distribution, and Installation:** Documented system for handling and storing raw materials, in-process product, and finished goods so that the materials remain undamaged and the correct materials can be provided as required. Records of distribution are maintained to facilitate possible product recalls. If device is

installed, there is a defined system for installations, and documentation of correct installation if performed by the manufacturer.

**Subpart M – Records, DMR, DHR, and Customer Complaints:** Documented requirements for what quality records must be maintained and for how long. Records provided to FDA in an audit can be marked “confidential” as a way of requesting that they are not made available to the public in Freedom of Information requests. Management Review reports, Internal Audit reports, and supplier audit reports are not subject to FDA review during routine FDA audits. A documented general “Quality System Record” of non-device specific documents is required.

A **Device Master Record (DMR)** is generated to include reference to *what is required* to produce a specific device. The DMR is generated from the design control process.

A **Device History Record (DHR)** is generated *for every lot of product produced*, defining all materials, methods, equipment, personnel, documents etc. involved in or used to manufacture a specific device batch, lot, or serial number.

The manufacturer has a documented system for receiving, screening, investigating, initiating corrective action, and/or otherwise resolving customer complaints.

**Subpart N – Servicing:** A documented system for defining and executing service programs. Records of service are maintained. Although the regulation does not explicitly state requirements for technical support programs, controls need to be in place, including links to the complaint handling system.

**Subpart O – Statistical Techniques:** Documented system for using statistical techniques, for example: sampling plans used in incoming inspection, control charting used to monitor production processes, and report trends used in management review meetings.

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<sup>1</sup> Based on an overview provided by Michelle Paganini of Michelle Paganini Associates. Reprinted with permission.