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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES
PART 820--QUALITY MANAGEMENT SYSTEM REGULATION
(Proposed Rule)

Contents

Subpart A--General Provisions

§ 820.1 Scope.

(a) Applicability. Current good manufacturing practice (CGMP) requirements are set forth in this quality management system regulation (QMSR). The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to assure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act. Any manufacturers engaged in the design, manufacture, packaging, labeling, storage, installation, or servicing of a finished device must establish and maintain a quality management system that is appropriate for its specific device(s). Manufacturers subject to this part include, but are not limited to, manufacturers that perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, as well as initial distributors of foreign entities that perform these functions. If a manufacturer engages in only

some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged.

(1) Finished devices. The provisions of this part shall apply to any finished device, as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(2) Components or parts. The provisions of this part do not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to consider provisions of this regulation as appropriate.

(3) Blood and blood components. The provisions of this part do not apply to manufacturers of blood and blood components used for transfusion or for further manufacturing. Such manufacturers are subject to subchapter F of this chapter.

(4) HCT/Ps. The provisions of this part apply to manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in § 1271.3(d) of this chapter, that are devices (subject to premarket review or notification, or exempt from notification, under an application submitted under the device provisions of the Federal Food, Drug, and Cosmetic Act or under a biological product license application under section 351 of the Public Health Service Act). HCT/Ps regulated as devices are also subject to the donor-eligibility requirements set forth in part 1271, subpart C of this chapter and applicable current good tissue practice requirements in part 1271, subpart D of this chapter. In the event of a conflict between applicable regulations in part 1271 and in other parts of this chapter, the regulation specifically applicable to the device in question shall supersede the more general regulation.

(b) Conflicts with other requirements under the Federal Food, Drug, and Cosmetic Act.

The QMSR for devices in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event of a conflict between applicable regulations in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede the more generally applicable regulations to the extent they conflict.

Moreover, to the extent that any clauses of ISO 13485 (incorporated by reference, see § 820.7) conflict with any provisions of the Federal Food, Drug, and Cosmetic Act and/or its other implementing regulations, the Federal Food, Drug, and Cosmetic Act and/or its other implementing regulations will control.

(c) Foreign manufacturers. If it appears that an owner, operator, or agent of any factory, warehouse, or establishment who offers devices for import into the United States delays, denies, or limits an inspection, or refuses to permit entry or inspection of the foreign facility for the purpose of determining compliance with this part, or the methods used in, and the facilities and controls used for, the manufacture, packing, storage, installation, processing, or held in such factory, warehouse, or establishment that are offered for import into the United States do not conform to the requirements of section 520(f) of the Federal Food, Drug, and Cosmetic Act and this part, then the devices manufactured at that facility are adulterated under section 501(h) or (j) of the Federal Food, Drug, and Cosmetic Act and will be refused admission to the United States under section 801(a) of the Federal Food, Drug, and Cosmetic Act.

(d) Exemptions or variances.

(1) A manufacturer subject to any requirement under section 520(f)(1) of the Federal Food, Drug, and Cosmetic Act, including any requirements under this part, may petition for an exemption or variance from such requirement in accordance with section 520(f)(2) of the Federal Food, Drug, and Cosmetic Act. Petitions for an exemption or variance shall be submitted in accordance with the procedures set forth in § 10.30 of this chapter.

(2) FDA may initiate and grant a variance from any requirement(s) in this part when the Agency determines that such variance is in the best interest of the public health. Such variance will remain in effect only so long as there remains a public health need for the device and the device would not likely be made sufficiently available without the variance.

§ 820.3 Definitions.
The definitions in ISO 13485 (incorporated by reference, see § 820.7) apply to this part, except as specified in paragraph (b) of this section, and do not affect the meaning of similar terms defined in this title.

(a) The following terms are necessary for the purposes of this part and do not appear in ISO 13485:

Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly that is intended to be included as part of the finished, packaged, and labeled device.

Customer means persons or organizations, including users, that could or do receive a product or a service that is intended for or required by this person or organization. A customer can be internal or external to the organization.

Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s).

Federal Food, Drug, and Cosmetic Act means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., as amended.

Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) of this chapter and that is also regulated as a device.

Nonconformity means the nonfulfillment of a specified requirement.

Process agent means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.

Process validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

Remanufacturer means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device’s performance or safety specifications, or intended use.

Rework means action taken on a nonconforming product so that it will fulfill the specified requirements before it is released for distribution.

Top management means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality management system.

Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

(b) All definitions in section 201 of the Federal Food, Drug, and Cosmetic Act shall apply to the regulation of quality management systems under this part and shall supersede the correlating terms and definitions in ISO 13485 (e.g., the definitions of device and labeling in sections 201(h) and (m) of the Federal Food, Drug, and Cosmetic Act apply to this part and supersede the definitions for the correlating terms in ISO 13485 (labelling and medical device)). In addition, the following terms and definitions supersede the correlating term and definition in ISO 13485:

Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes, but is not limited to, those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

Product means components, process agents, in-process devices, finished devices, and returned devices.

§ 820.5 [Reserved]

§ 820.7 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration, Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, email fr.inspection@nara.gov, or go to

www.archives.gov/federal-register/cfr/ibr-locations.html

It is available from the following source(s):

(a) The International Organization for Standardization (ISO), BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; +41-22-749-01-11; customerservice@iso.org https://www.iso.org/store.html

(1) ISO 13485, "Medical devices--Quality management systems--Requirements for regulatory purposes," third edition, dated March 2016; IBR approved for §§ 820.1; 820.3; 820.10; 820.15; 820.35; 820.45.

(2) [Reserved]

(b) [Reserved]

§ 820.10 Requirements for a quality management system.

A manufacturer subject to this part as described by § 820.1(a) must:

(a) Document. Document a quality management system that complies with the requirements of ISO 13485 (incorporated by reference, see § 820.7) and this part; and

(b) Applicable regulatory requirements. Comply, as appropriate, with the other applicable regulatory requirements in this title, including, but not limited to the following, to fully comply with the listed ISO 13485 Clause:

(1) For Clause 7.5.8 in ISO 13485, Identification, the manufacturer must document a system to assign unique device identification to the medical device in accordance with the requirements of part 830.

(2) For Clause 7.5.9.1 in ISO 13485, Traceability--General, the manufacturer must document procedures for traceability in accordance with the requirements of part 821, if applicable.

(3) For Clause 8.2.3 in ISO 13485, Reporting to regulatory authorities, the manufacturer must notify FDA of complaints that meet the reporting criteria of part 803 of this chapter.

(4) For Clauses 7.2.3, 8.2.3, and 8.3.3, advisory notices shall be handled in accordance with the requirements of part 806.

(c) Design and Development. Manufacturers of class II, class III, and those class I devices listed below must comply with the requirements in Design and Development, Clause 7.3 and its Subclauses in ISO 13485. The class I devices are as follows:

(1) Devices automated with computer software; and

(2) The devices listed in the following table:

Table 1 to paragraph (c)(2)

Section	Device
868.6810	Catheter, Tracheobronchial Suction.
878.4460	Glove, Non-powdered Surgeon's.
880.6760	Restraint, Protective.
892.5650	System, Applicator, Radionuclide, Manual.
892.5740	Source, Radionuclide Teletherapy.

(d) Devices that support or sustain life. Manufacturers of devices that support or sustain life, the failure of which to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury, must comply with the requirements in Traceability for Implantable Devices, Clause 7.5.9.2 in ISO 13485, in addition to all other requirements in this part, as appropriate.

(e) Enforcement. The failure to comply with any applicable requirement in this part renders a device adulterated under section 501(h) of the Federal Food, Drug, and Cosmetic Act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.

§ 820.15 Clarification of concepts.
Manufacturers subject to this part shall construe the following terms in ISO 13485 (incorporated by reference, see § 820.7) as follows:

(a) Organization shall have the meaning of "manufacturers" as defined in this part.

(b) Safety and performance shall have the meaning of "safety and effectiveness" for the purposes of this part. The phrase "safety and performance" does not relieve a manufacturer from any obligation to implement controls or other measures that provide reasonable assurance of safety and effectiveness.

(c) Validation of processes shall have the meaning of "process validation" as defined in this part.

Subpart B--Supplemental Provisions

§ 820.20 – § 820.30 [Reserved]

§ 820.35 Control of records.

In addition to the requirements of Clause 4.2.5 in ISO 13485 (incorporated by reference, see § 820.7), Control of Records, the manufacturer must obtain the signature for each individual who approved or re-approved the record, and the date of such approval, on that record and include the below information in certain records as follows:

(a) Records of complaints. In addition to Clause 8.2.2 in ISO 13485, Complaint Handling, the manufacturer must record the following information, at a minimum, for complaints that must be reported to FDA under part 803 of this chapter, complaints that a manufacturer determines must be investigated, and complaints that the manufacturer investigated regardless of those requirements:

(1) The name of the device;

(2) The date the complaint was received;

(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s);

(4) The name, address, and phone number of the complainant;

(5) The nature and details of the complaint;

(6) Any corrective action taken; and

(7) Any reply to the complainant.

(b) Records of servicing activities. In adhering to Clause 7.5.4 in ISO 13485, Servicing Activities, the manufacturer must record the following information, at a minimum, for servicing activities:

(1) The name of the device serviced;

(2) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s);

(3) The date of service;

(4) The individual(s) who serviced the device;

(5) The service performed; and

(6) Any test and inspection data.

(c) Unique device identification. In addition to the requirements of Clauses 7.5.1, 7.5.8, and 7.5.9 in ISO 13485, the UDI must be recorded for each medical device or batch of medical devices.

(d) Confidentiality. Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.

§ 820.40 [Reserved]

§ 820.45 Device labeling and packaging controls.

In addition to the requirements of Clause 7.5.1 of ISO 13485 (incorporated by reference, see § 820.7), Control of production and service provision, each manufacturer must establish and maintain procedures that provide a detailed description of the activities to ensure the integrity, inspection, storage, and operations for labeling and packaging, during the customary conditions of processing, storage, handling, distribution, and where appropriate, use of the device.

(a) The manufacturer must ensure labeling and packaging has been examined for accuracy prior to release or storage, where applicable, to include the following:

(1) The correct unique device identifier (UDI) or universal product code (UPC), or any other device identification(s);

(2) Expiration date;

(3) Storage instructions;

(4) Handling instructions; and

(5) Any additional processing instructions.

(b) The release of the labeling for use must be documented in accordance with Clause 4.2.5 of ISO 13485.

(c) The manufacturer must ensure labeling and packaging operations have been established and maintained to prevent errors, including, but not limited to, inspection of the labeling and packaging immediately before use to assure that all devices have correct labeling and packaging, as specified in the medical device file. Results of such labeling inspection must be documented in accordance with Clause 4.2.5 of ISO 13485.

Subparts C-O [Reserved]

About Us

Quality Systems Compliance LLC primarily works with companies in the FDA regulated industries (medical devices, human tissue, animal tissue, cosmetics, and pharmaceuticals) focusing on quality management system implementation, integration, updates, and training. Additionally, Quality Systems Compliance LLC assists companies by providing internal and external (supplier and due diligence) audit support as well as FDA 483 and Warning Letter response and remediation services.