

§ 814.126 Postapproval requirements and reports.

(a) An HDE approved under this subpart H shall be subject to the postapproval requirements and reports set forth under subpart E of this part, as applicable, with the exception of § 814.82(a)(7). In addition, medical device reports submitted to FDA in compliance with the requirements of part 803 of this chapter shall also be submitted to the IRB of record.

(b) In addition to the reports identified in paragraph (a) of this section, the holder of an approved HDE shall prepare and submit the following complete, accurate, and timely reports:

(1) *Periodic reports.* An HDE applicant is required to submit reports in accordance with the approval order. Unless FDA specifies otherwise, any periodic report shall include:

(i) An update of the information required under § 814.102(a) in a separately bound volume;

(ii) An update of the information required under § 814.104(b)(2), (b)(3), and (b)(5);

(iii) The number of devices that have been shipped or sold since initial marketing approval under this subpart H and, if the number shipped or sold exceeds 4,000, an explanation and estimate of the number of devices used per patient. If a single device is used on multiple patients, the applicant shall submit an estimate of the number of patients treated or diagnosed using the device together with an explanation of the basis for the estimate;

(iv) Information describing the applicant's clinical experience with the device since the HDE was initially approved. This information shall include safety information that is known or reasonably should be known to the applicant, medical device reports made under part 8dd of this chapter, any data generated from the postmarketing studies, and information (whether published or unpublished) that is known or reasonably expected to be known by the applicant that may affect an evaluation of the safety of the device or that may affect the statement of contraindications, warnings, precautions, and adverse reactions in the device's labeling; and

(v) A summary of any changes made to the device in accordance with supplements submitted under § 814.108. If information provided in the periodic reports, or any other information in the possession of FDA, gives the agency reason to believe that a device raises public health concerns or that the criteria for exemption are no longer met, the agency may require the HDE holder to submit additional information to demonstrate continued compliance with the HDE requirements.

(2) *Other.* An HDE holder shall maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing IRB's, as well as any other information requested by a reviewing IRB or FDA. Such records shall be maintained in accordance with the HDE approval order.

[61 FR 33244, June 26, 1996, as amended at 63 FR 59221, Nov. 3, 1998]

PART 820—QUALITY SYSTEM REGULATION**Subpart A—General Provisions**

Sec.	
820.1	Scope.
820.3	Definitions.
820.5	Quality system.

Subpart B—Quality System Requirements

820.20	Management responsibility.
820.22	Quality audit.
820.25	Personnel.

Subpart C—Design Controls

820.30	Design controls.
--------	------------------

Subpart D—Document Controls

820.40	Document controls.
--------	--------------------

Subpart E—Purchasing Controls

820.50	Purchasing controls.
--------	----------------------

Subpart F—Identification and Traceability

820.60	Identification.
820.65	Traceability.

Subpart G—Production and Process Controls

820.70	Production and process controls.
820.72	Inspection, measuring, and test equipment.

§ 820.1

21 CFR Ch. I (4–1–05 Edition)

820.75 Process validation.

Subpart H—Acceptance Activities

820.80 Receiving, in-process, and finished device acceptance.

820.86 Acceptance status.

Subpart I—Nonconforming Product

820.90 Nonconforming product.

Subpart J—Corrective and Preventive Action

820.100 Corrective and preventive action.

Subpart K—Labeling and Packaging Control

820.120 Device labeling.

820.130 Device packaging.

Subpart L—Handling, Storage, Distribution, and Installation

820.140 Handling.

820.150 Storage.

820.160 Distribution.

820.170 Installation.

Subpart M—Records

820.180 General requirements.

820.181 Device master record.

820.184 Device history record.

820.186 Quality system record.

820.198 Complaint files.

Subpart N—Servicing

820.200 Servicing.

Subpart O—Statistical Techniques

820.250 Statistical techniques.

AUTHORITY: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383.

EFFECTIVE DATE NOTE: At 69 FR 29829, May 25, 2004, the authority citation for part 1271 was revised, effective May 25, 2005. For the convenience of the user, the revised text is set forth as follows:

AUTHORITY: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

SOURCE: 61 FR 52654, Oct. 7, 1996, unless otherwise noted.

Subpart A—General Provisions

§ 820.1 Scope.

(a) *Applicability.* (1) Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. 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 ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices. 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. With respect to class I devices, design controls apply only to those devices listed in § 820.30(a)(2). This regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance. Manufacturers of human blood and blood components are not subject to this part, but are subject to part 606 of this chapter.

(2) The provisions of this part shall be applicable 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.

(3) In this regulation the term “where appropriate” is used several times. When a requirement is qualified by “where appropriate,” it is deemed to be “appropriate” unless the manufacturer can document justification otherwise. A requirement is “appropriate” if nonimplementation could reasonably be expected to result in the product not meeting its specified requirements or the manufacturer not being able to carry out any necessary corrective action.

(b) *Limitations.* The quality system regulation in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event that it is impossible to comply with all applicable regulations, both in this part and in other

parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other generally applicable requirements.

(c) *Authority.* Part 820 is established and issued under authority of sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383). The failure to comply with any applicable provision in this part renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.

(d) *Foreign manufacturers.* If a manufacturer who offers devices for import into the United States refuses to permit or allow the completion of a Food and Drug Administration (FDA) inspection of the foreign facility for the purpose of determining compliance with this part, it shall appear for purposes of section 801(a) of the act, that the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, or servicing of any devices produced at such facility that are offered for import into the United States do not conform to the requirements of section 520(f) of the act and this part and that the devices manufactured at that facility are adulterated under section 501(h) of the act.

(e) *Exemptions or variances.* (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in §10.30 of this chapter, the FDA's administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1-800-638-2041 or 1-301-443-6597, FAX 301-443-8818.

(2) FDA may initiate and grant a variance from any device quality system requirement 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.

[61 FR 52654, Oct. 7, 1996, as amended at 65 FR 17136, Mar. 31, 2000; 65 FR 66636, Nov. 7, 2000]

EFFECTIVE DATE NOTE: At 69 FR 29829, May 25, 2004, §820.1 was amended by adding two sentences to the end of paragraph (a)(1) and by revising paragraph (b), effective May 25, 2005. For the convenience of the user, the added and revised text is set forth as follows:

§ 820.1 Scope.

(a) *Applicability.* (1) * * * Manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in §1271.3(d) of this chapter, that are medical devices (subject to premarket review or notification, or exempt from notification, under an application submitted under the device provisions of the act or under a biological product license application under section 351 of the Public Health Service Act) are subject to this part and are also subject to the donor-eligibility procedures set forth in part 1271 subpart C of this chapter and applicable current good tissue practice procedures 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.

* * * * *

(b) The quality system regulation 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 any other generally applicable requirements.

* * * * *

§ 820.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-903, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 321-394)). All definitions in section 201 of the act shall apply to the regulations in this part.

(b) *Complaint* means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.