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

(bb) **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) and that is also regulated as a device.

(cc) **Unique device identifier (UDI)** means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of §830.20 of this chapter. A unique device identifier is composed of:

1. A **device identifier**—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and
2. A **production identifier**—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
   i. The lot or batch within which a device was manufactured;
   ii. The serial number of a specific device;
   iii. The expiration date of a specific device;
   iv. The date a specific device was manufactured.

(v) For an HCT/P regulated as a device, the distinct identification code required by §1271.290(c) of this chapter.

(dd) **Universal product code (UPC)** means the product identifier used to identify an item sold at retail in the United States.


§ 820.20 **Management responsibility.**

Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.

### Subpart B—Quality System Requirements

§ 820.20 **Management responsibility.**

(a) **Quality policy.** Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.

(b) **Organization.** Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part.

1. **Responsibility and authority.** Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.

2. **Resources.** Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.

3. **Management representative.** Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:

   i. Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and

   ii. Reporting on the performance of the quality system to management with executive responsibility for review.

(c) **Management review.** Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer’s established quality policy and objectives. The dates and results of quality system reviews shall be documented.

(d) **Quality planning.** Each manufacturer shall establish a quality plan
which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured. The manufacturer shall establish how the requirements for quality will be met.

(e) Quality system procedures. Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.

§ 820.22 Quality audit.
Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented.

§ 820.25 Personnel.

(a) General. Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.

(b) Training. Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.

(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.

(2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

§ 820.30 Design controls.

(a) General. (1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

(2) The following class I devices are subject to design controls:

(i) Devices automated with computer software; and

(ii) The devices listed in the following chart.

(b) Design and development planning. Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.

(c) Design input. Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

(d) Design output. Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output...