subpart clarifies the application of current good manufacturing practice regulations to combination products, and provides a regulatory framework for designing and implementing the current good manufacturing practice operating system at facilities that manufacture co-packaged or single-entity combination products.

§ 4.2 How does FDA define key terms and phrases in this subpart?

The terms listed in this section have the following meanings for purposes of this subpart:

**Biological product** has the meaning set forth in § 3.2(d) of this chapter. A biological product also meets the definitions of either a drug or device as these terms are defined under this section.

**Combination product** has the meaning set forth in § 3.2(e) of this chapter.

**Constituent part** is a drug, device, or biological product that is part of a combination product.

**Co-packaged combination product** has the meaning set forth in § 3.2(e)(2) of this chapter.

**Current good manufacturing practice operating system** means the operating system within an establishment that is designed and implemented to address and meet the current good manufacturing practice requirements for a combination product.

**Current good manufacturing practice requirements** means the requirements set forth under § 4.3(a) through (d).

**Device** has the meaning set forth in § 3.2(f) of this chapter. A device that is a constituent part of a combination product is considered a finished device within the meaning of the QS regulation.

**Drug** has the meaning set forth in § 3.2(g) of this chapter. A drug that is a constituent part of a combination product is considered a drug product within the meaning of the drug CGMPs.

**Drug CGMPs** refers to the current good manufacturing practice regulations set forth in parts 210 and 211 of this chapter.

**HCT/Ps** refers to human cell, tissue, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter. An HCT/P that is not solely regulated under section 361 of the Public Health Service Act may be a constituent part of a combination product. Such an HCT/P is subject to part 1271 of this chapter and is also regulated as a drug, device, and/or biological product.

**Manufacture** includes, but is not limited to, designing, fabricating, assembling, filling, processing, testing, labeling, packaging, repackaging, holding, and storage.

**QS regulation** refers to the quality system regulation in part 820 of this chapter.

**Single-entity combination product** has the meaning set forth in § 3.2(e)(1) of this chapter.

**Type of constituent part** refers to the category of the constituent part, which can be either a biological product, a device, or a drug, as these terms are defined under this section.

§ 4.3 What current good manufacturing practice requirements apply to my combination product?

If you manufacture a combination product, the requirements listed in this section apply as follows:

(a) The current good manufacturing practice requirements in parts 210 and 211 of this chapter apply to a combination product that includes a drug constituent part;

(b) The current good manufacturing practice requirements in part 820 of this chapter apply to a combination product that includes a device constituent part;

(c) The current good manufacturing practice requirements among the requirements (including standards) for biological products in parts 600 through 680 of this chapter apply to a combination product that includes a biological product constituent part to which those requirements would apply if that constituent part were not part of a combination product; and

(d) The current good tissue practice requirements including donor eligibility requirements for HCT/Ps in part 1271 of this chapter apply to a combination product that includes an HCT/P.

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