§ 211.1 Scope.

(a) The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products (excluding positron emission tomography drugs) for administration to humans or animals.

(b) The current good manufacturing practice regulations in this chapter as they pertain to drug products; in parts 600 through 680 of this chapter, as they pertain to drugs that are also biologic products for human use; and in part 1271 of this chapter, as they are applicable to drugs that are also human cells, tissues, and cellular and tissue-based products (HCT/Ps) and that are drugs (subject to review under an application submitted under section 505 of

Subpart C—Buildings and Facilities

211.42 Design and construction features.
211.44 Lighting.
211.46 Ventilation, air filtration, air heating and cooling.
211.48 Plumbing.
211.50 Sewage and refuse.
211.52 Washing and toilet facilities.
211.56 Sanitation.
211.58 Maintenance.

Subpart D—Equipment

211.63 Equipment design, size, and location.
211.65 Equipment construction.
211.67 Equipment cleaning and maintenance.
211.69 Automatic, mechanical, and electronic equipment.
211.72 Filters.

Subpart E—Control of Components and Drug Product Containers and Closures

211.80 General requirements.
211.82 Receipt and storage of untested components, drug product containers, and closures.
211.84 Testing and approval or rejection of components, drug product containers, and closures.
211.86 Use of approved components, drug product containers, and closures.
211.87 Retesting of approved components, drug product containers, and closures.
211.89 Rejected components, drug product containers, and closures.
211.94 Drug product containers and closures.

Subpart F—Production and Process Controls

211.100 Written procedures; deviations.
211.101 Charge-in of components.
211.103 Calculation of yield.
211.105 Equipment identification.
211.110 Sampling and testing of in-process materials and drug products.
211.111 Time limitations on production.
211.113 Control of microbiological contamination.
211.115 Reprocessing.

Subpart G—Packaging and Labeling Control

211.122 Materials examination and usage criteria.
211.125 Labeling issuance.
211.130 Packaging and labeling operations.
211.132 Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.
211.134 Drug product inspection.
§ 211.3 Definitions.

The definitions set forth in § 210.3 of this chapter apply in this part.

Subpart B—Organization and Personnel

§ 211.22 Responsibilities of quality control unit.

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

(b) Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit.

(c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

(d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed.

§ 211.25 Personnel qualifications.

(a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee’s functions.

(b) Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.

(c) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product.