

# 21 Code of Federal Regulations Parts 210, 211 and 11

## EU GMP Guidelines Volume 4 Ch. 1-9 and Part II



### 21 CFR Part 210

Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General

### 21 CFR Part 211

Current Good Manufacturing Practice for Finished Pharmaceuticals

### 21 CFR Part 11

Electronic Records; Electronic Signatures

### EU Guidelines for GMP, Chapter 1-9

Medicinal Products for Human and Veterinary Use

### EU Guidelines for GMP, Part II

Basic Requirements for Active Substances used as Starting Materials

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## 21 CFR 210

### Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General

Revised as of April 1, 2006

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## Subpart C – Buildings and Facilities

### §211.42 Design and construction features

- (a) Any building or buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations.
- (b) Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination. The flow of components, drug product containers, closures, labeling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination.
- (c) Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas for the firm's operations to prevent contamination or mixups as follows:
- (1) Receipt, identification, storage, and withholding from use of components, drug product containers, closures, and labeling, pending the appropriate sampling, testing, or examination by the quality control unit before release for manufacturing or packaging;
  - (2) Holding rejected components, drug product containers, closures, and labeling before disposition;
  - (3) Storage of released components, drug product containers, closures, and labeling;
  - (4) Storage of in-process materials;
  - (5) Manufacturing and processing operations;
  - (6) Packaging and labeling operations;
  - (7) Quarantine storage before release of drug products;
  - (8) Storage of drug products after release;
  - (9) Control and laboratory operations;
  - (10) Aseptic processing, which includes as appropriate:
    - (i) Floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable;
    - (ii) Temperature and humidity controls;
    - (iii) An air supply filtered through high-efficiency particulate air filters under positive pressure, regardless of whether flow is laminar or nonlaminar;

- (iv) A system for monitoring environmental conditions;
  - (v) A system for cleaning and disinfecting the room and equipment to produce aseptic conditions;
  - (vi) A system for maintaining any equipment used to control the aseptic conditions.
- (d) Operations relating to the manufacture, processing, and packing of penicillin shall be performed in facilities separate from those used for other drug products for human use.
- [43 FR 45077, Sept. 29, 1978, as amended at 60 FR 4091, Jan. 20, 1995]

### §211.44 Lighting

Adequate lighting shall be provided in all areas.

### §211.46 Ventilation, air filtration, air heating and cooling

- (a) Adequate ventilation shall be provided.
- (b) Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing, or holding of a drug product.
- (c) Air filtration systems, including prefilters and particulate matter air filters, shall be used when appropriate on air supplies to production areas. If air is recirculated to production areas, measures shall be taken to control recirculation of dust from production. In areas where air contamination occurs during production, there shall be adequate exhaust systems or other systems adequate to control contaminants.
- (d) Air-handling systems for the manufacture, processing, and packing of penicillin shall be completely separate from those for other drug products for human use.

### §211.48 Plumbing

- (a) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any drug product. Potable water shall meet the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations set forth in 40 CFR part 141. Water not meeting such standards shall not be permitted in the potable water system.

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