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## SEARCH CRITERIA...

*In STEP 1 you selected:*

Drugs, Biologics, API, Medical Device

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FDA Regulations, EC Support Documents, FDA Warning Letters, EC Regulations, FDA Support Documents, FDA 483 Observations

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All records.

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## 21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (01 April 2003)

### Subpart C - Buildings and Facilities

#### 21 CFR 211.42 Design and Construction Features (a)

ViP ID: 18

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.

### Subpart C - Buildings and Facilities

#### 21 CFR 211.42 Design and Construction Features (b)

ViP ID: 19

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.

### Subpart C - Buildings and Facilities

#### 21 CFR 211.42 Design and Construction Features (c)

ViP ID: 20

Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures:

- (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.

### Subpart C - Buildings and Facilities

#### 21 CFR 211.42 Design and Construction Features (d)

ViP ID: 37

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]

**Subpart C - Buildings and Facilities**  
**21 CFR 211.44 Lighting**

ViP ID: 38

Adequate lighting shall be provided in all areas.

**Subpart C - Buildings and Facilities**  
**21 CFR 211.46 Ventilation, Air Filtration, Air Heating and Cooling (c)**

ViP ID: 41

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.

**Subpart C - Buildings and Facilities**  
**21 CFR 211.46 Ventilation, Air Filtration, Air Heating and Cooling (d)**

ViP ID: 42

Air-handling systems for the manufacture, processing, and packing of penicillin shall be completely separate from those for other drug products for human use.

**Subpart C - Buildings and Facilities**  
**21 CFR 211.48 Plumbing (b)**

ViP ID: 44

Drains shall be of adequate size and, where connected directly to a sewer, shall be provided with an air break or other mechanical device to prevent back-siphonage.

[43 FR 45077, Sept. 29, 1978, as amended at 48 FR 11426, Mar. 18, 1983]

**Subpart C - Buildings and Facilities**  
**21 CFR 211.52 Washing and Toilet Facilities**

ViP ID: 46

Adequate washing facilities shall be provided, including hot and cold water, soap or detergent, air driers or single-service towels, and clean toilet facilities easily accessible to working areas.

**Subpart C - Buildings and Facilities**  
**21 CFR 211.56 Sanitation (a)**

ViP ID: 47

Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a clean and sanitary condition. Any such building shall be free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals). Trash and organic waste matter shall be held and disposed of in a timely and sanitary manner.

**Subpart C - Buildings and Facilities**  
**21 CFR 211.58 Maintenance**

ViP ID: 51

Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a good state of repair.

**Subpart D - Equipment**  
**21 CFR 211.63 Equipment Design, Size and Location**

ViP ID: 52

Equipment used in the manufacture, processing, packing, or holding of a drug product shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.

**Subpart D - Equipment**  
**21 CFR 211.65 Equipment Construction (a)**

ViP ID: 53

Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

**Subpart D - Equipment**  
**21 CFR 211.65 Equipment Cleaning and Maintenance (b)**

ViP ID: 54

Any substances required for operation, such as lubricants or coolants, shall not come into contact with components, drug product containers, closures, in-process materials, or drug products so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

**Subpart D - Equipment**  
**21 CFR 211.67 Equipment Cleaning and Maintenance (a)**

ViP ID: 55

Equipment and utensils shall be cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

**Subpart D - Equipment**  
**21 CFR 211.67 Equipment Cleaning and Maintenance (b)**

ViP ID: 56

Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following:

- (1) Assignment of responsibility for cleaning and maintaining equipment;
- (2) Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules;
- (3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance;
- (4) Removal or obliteration of previous batch identification;
- (5) Protection of clean equipment from contamination prior to use;
- (6) Inspection of equipment for cleanliness immediately before use.

## **Subpart D - Equipment**

### **21 CFR 211.68 Automatic, Mechanical, and Electronic Equipment (a)**

ViP ID: 64

Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained.

## **Subpart D - Equipment**

### **21 CFR 211.72 Filters**

ViP ID: 66

Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use shall not release fibers into such products. Fiber-releasing filters may not be used in the manufacture, processing, or packing of these injectable drug products unless it is not possible to manufacture such drug products without the use of such filters. If use of a fiber-releasing filter is necessary, an additional non-fiber-releasing filter of 0.22 micron maximum mean porosity (0.45 micron if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of particles in the injectable drug product. Use of an asbestos-containing filter, with or without subsequent use of a specific non-fiber-releasing filter, is permissible only upon submission of proof to the appropriate bureau of the Food and Drug Administration that use of a non-fiber-releasing filter will, or is likely to, compromise the safety or effectiveness of the injectable drug product.

## **Subpart E-Control of Components and Drug Product Containers and Closures**

### **21 CFR 211.94 Drug Product Containers and Closures (a)**

ViP ID: 93

Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements.

## **Subpart F- Production and Process Controls**

### **21 CFR 211.105 Equipment Identification (a)**

ViP ID: 112

All compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product shall be properly identified at all times to indicate their contents and, when necessary, the phase of processing of the batch.

## **Subpart F- Production and Process Controls**

### **21 CFR 211.105 Equipment Identification (b)**

ViP ID: 113

Major equipment shall be identified by a distinctive identification number or code that shall be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the name of the equipment may be used in lieu of a distinctive identification number or code.

## **Subpart I - Laboratory Controls**

### **21 CFR 211.160 General Requirements (b) (4)**

ViP ID: 184

Laboratory controls shall include:

The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used.

## **Subpart J - Records and Reports**

### **21 CFR 211.182 Equipment Cleaning and Use Log**

ViP ID: 223

A written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed. If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order.

## **Subpart J - Records and Reports**

### **21 CFR 211.194 Laboratory Records (d)**

ViP ID: 256

Complete records shall be maintained of the periodic calibration of laboratory instruments, apparatus, gauges, and recording devices required by § 211.160(b)(4).

## 21 CFR PART 600 - BIOLOGICAL PRODUCTS: GENERAL (01 April 2003)

### Subpart B--Establishment Standards

#### 21 CFR 600.11 Physical establishment, equipment, animals, and care. (a)

VIP ID: 1850

Work areas. All rooms and work areas where products are manufactured or stored shall be kept orderly, clean, and free of dirt, dust, vermin and objects not required for manufacturing. Precautions shall be taken to avoid clogging and back-siphonage of drainage systems. Precautions shall be taken to exclude extraneous infectious agents from manufacturing areas. Work rooms shall be well lighted and ventilated. The ventilation system shall be arranged so as to prevent the dissemination of microorganisms from one manufacturing area to another and to avoid other conditions unfavorable to the safety of the product. Filling rooms, and other rooms where open, sterile operations are conducted, shall be adequate to meet manufacturing needs and such rooms shall be constructed and equipped to permit thorough cleaning and to keep air-borne contaminants at a minimum. If such rooms are used for other purposes, they shall be cleaned and prepared prior to use for sterile operations. Refrigerators, incubators and warm rooms shall be maintained at temperatures within applicable ranges and shall be free of extraneous material which might affect the safety of the product.

### Subpart B--Establishment Standards

#### 21 CFR 600.11 Physical establishment, equipment, animals, and care. (b)

VIP ID: 1851

Equipment. Apparatus for sterilizing equipment and the method of operation shall be such as to insure the destruction of contaminating microorganisms. The effectiveness of the sterilization procedure shall be no less than that achieved by an attained temperature of 121.5° C maintained for 20 minutes by saturated steam or by an attained temperature of 170° C maintained for 2 hours with dry heat. Processing and storage containers, filters, filling apparatus, and other pieces of apparatus and accessory equipment, including pipes and tubing, shall be designed and constructed to permit thorough cleaning and, where possible, inspection for cleanliness. All surfaces that come in contact with products shall be clean and free of surface solids, leachable contaminants, and other materials that will hasten the deterioration of the product or otherwise render it less suitable for the intended use. For products for which sterility is a factor, equipment shall be sterile, unless sterility of the product is assured by subsequent procedures.

### Subpart B--Establishment Standards

#### 21 CFR 600.11 Physical establishment, equipment, animals, and care. (c)

VIP ID: 1852

Laboratory and bleeding rooms. Rooms used for the processing of products, including bleeding rooms, shall be effectively fly-proofed and kept free of flies and vermin. Such rooms shall be so constructed as to insure freedom from dust, smoke and other deleterious substances and to permit thorough cleaning and disinfection. Rooms for animal injection and bleeding, and rooms for smallpox vaccine animals, shall be disinfected and be provided with the necessary water, electrical and other services.

### Subpart B--Establishment Standards

#### 21 CFR 600.11 Physical establishment, equipment, animals, and care. (d)

VIP ID: 1853

Animal quarters and stables. Animal quarters, stables and food storage areas shall be of appropriate construction, fly-proofed, adequately lighted and ventilated, and maintained in a clean, vermin-free and sanitary condition. No manure or refuse shall be stored as to permit the breeding of flies on the premises, nor shall the establishment be located in close proximity to off-property manure or refuse storage capable of engendering fly breeding.

## Subpart B--Establishment Standards

### 21 CFR 600.11 Physical establishment, equipment, animals, and care. (e)

ViP ID: 1854

#### Restrictions on building and equipment use

(1) Work of a diagnostic nature. Laboratory procedures of a clinical diagnostic nature involving materials that may be contaminated, shall not be performed in space used for the manufacture of products except that manufacturing space which is used only occasionally may be used for diagnostic work provided spore-bearing pathogenic microorganisms are not involved and provided the space is thoroughly cleaned and disinfected before the manufacture of products is resumed.

(2) Spore-bearing organisms for supplemental sterilization procedure control test. Spore-bearing organisms used as an additional control in sterilization procedures may be introduced into areas used for the manufacture of products, only for the purposes of the test and only immediately before use for such purposes: Provided, That

(i) the organism is not pathogenic for man or animals and does not produce pyrogens or toxins,

(ii) the culture is demonstrated to be pure,

(iii) transfer of test cultures to culture media shall be limited to the sterility test area or areas designated for work with spore-bearing organisms,

(iv) each culture be labeled with the name of the microorganism and the statement "Caution: microbial spores. See directions for storage, use and disposition.", and

(v) the container of each culture is designed to withstand handling without breaking.

(3) Work with spore-bearing organisms. Except as provided in the previous paragraph, all work with spore-bearing microorganisms shall be done in an entirely separate building: Provided, That such work may be done in a portion of a building used in the manufacture of products not containing spore-bearing microorganisms if such portion is completely walled-off and is constructed so as to prevent contamination of other areas and if entrances to such portion are independent of the remainder of the building. All vessels, apparatus and equipment used for spore-bearing microorganisms shall be permanently identified and reserved exclusively for use with those organisms. Materials destined for further manufacturing may be removed from such an area only under conditions which will prevent the introduction of spores into other manufacturing areas.

(4) Live vaccine processing. Space used for processing a live vaccine shall not be used for any other purpose during the processing period for that vaccine and such space shall be decontaminated prior to initiation of the processing. Live vaccine processing areas shall be isolated from and independent of any space used for any other purpose by being either in a separate building, in a separate wing of a building, or in quarters at the blind end of a corridor and shall include adequate space and equipment for all processing steps up to filling into final containers. Test procedures which potentially involve the presence of microorganisms other than the vaccine strains, or the use of tissue culture cell lines other than primary cultures, shall not be conducted in space used for processing live vaccine.

(5) Equipment and supplies--contamination. Equipment and supplies used in work on or otherwise exposed to any pathogenic or potentially pathogenic agent shall be kept separated from equipment and supplies used in the manufacture of products to the extent necessary to prevent cross-contamination.

## Subpart B--Establishment Standards

### 21 CFR 600.11 Physical establishment, equipment, animals, and care. (f)

ViP ID: 1855

#### Animals used in manufacture

(1) Care of animals used in manufacturing. Caretakers and attendants for animals used for the manufacture of products shall be sufficient in number and have adequate experience to insure adequate care. Animal quarters and cages shall be kept in sanitary condition. Animals on production shall be inspected daily to observe response to production procedures. Animals that become ill for reasons not related to production shall be isolated from other animals and shall not be used for production until recovery is complete. Competent veterinary care shall be provided as needed.

#### (2) Quarantine of animals--

(i) General. No animal shall be used in processing unless kept under competent daily inspection and preliminary quarantine for a period of at least 7 days before use, or as otherwise provided in this subchapter. Only healthy animals free from detectable communicable diseases shall be used. Animals must remain in overt good health throughout the quarantine periods and particular care shall be taken during the quarantine periods to reject animals of the equine genus which may be infected with glanders and animals which may be infected with tuberculosis.

(ii) Quarantine of monkeys. In addition to observing the pertinent general quarantine requirements, monkeys used as a source of tissue in the manufacture of vaccine shall be maintained in quarantine for at least 6 weeks prior to use, except when otherwise provided in this part. Only monkeys that have reacted negatively to tuberculin at the start of the quarantine period and again within 2 weeks prior to use shall be used in the manufacture of vaccine. Due precaution shall be taken to prevent cross-infection from any infected or potentially infected monkeys on the premises. Monkeys to be used in the manufacture of a live vaccine shall be maintained throughout the quarantine period in cages closed on all sides with solid materials except the front which shall be screened, with no more than two monkeys housed in one cage. Cage mates shall not be interchanged.

(3) Immunization against tetanus. Horses and other animals susceptible to tetanus, that are used in the processing steps of the manufacture of biological products, shall be treated adequately to maintain immunity to tetanus.

(4) Immunization and bleeding of animals used as a source of products. Toxins or other nonviable antigens administered in the immunization of animals used in the manufacture of products shall be sterile. Viable antigens, when so used, shall be free of contaminants, as determined by appropriate tests prior to use. Injections shall not be made into horses within 6 inches of bleeding site. Horses shall not be bled for manufacturing purposes while showing persistent general reaction or local reaction near the site of bleeding. Blood shall not be used if it was drawn within 5 days of injecting the animals with viable microorganisms. Animals shall not be bled for manufacturing purposes when they have an intercurrent disease. Blood intended for use as a source of a biological product shall be collected in clean, sterile vessels. When the product is intended for use by injection, such vessels shall also be pyrogen-free.

#### (5) [Reserved]

(6) Reporting of certain diseases. In cases of actual or suspected infection with foot and mouth disease, glanders, tetanus, anthrax, gas gangrene, equine infectious anemia; equine encephalomyelitis, or any of the pock diseases among animals intended for use or used in the manufacture of products, the manufacturer shall immediately notify the Director, Center for Biologics Evaluation and Research.

(7) Monkeys used previously for experimental or test purposes. Monkeys that have been used previously for experimental or test purposes with live microbiological agents shall not be used as a source of kidney tissue for the manufacture of vaccine. Except as provided otherwise in this subchapter, monkeys that have been used previously for other experimental or test purposes may be used as a source of kidney tissue upon their return to a normal condition, provided all quarantine requirements have been met.

(8) Necropsy examination of monkeys. Each monkey used in the manufacture of vaccine shall be examined at necropsy under the direction of a qualified pathologist, physician, or veterinarian having experience with diseases of monkeys, for evidence of ill health, particularly for

- (i) evidence of tuberculosis,
- (ii) presence of herpes-like lesions, including eruptions or plaques on or around the lips, in the buccal cavity or on the gums, and
- (iii) signs of conjunctivitis.

If there are any such signs or other significant gross pathological lesions, the tissue shall not be used in the manufacture of vaccine.

## Subpart B--Establishment Standards

### 21 CFR 600.11 Physical establishment, equipment, animals, and care. (h)

ViP ID: 1857

Containers and closures. All final containers and closures shall be made of material that will not hasten the deterioration of the product or otherwise render it less suitable for the intended use. All final containers and closures shall be clean and free of surface solids, leachable contaminants and other materials that will hasten the deterioration of the product or otherwise render it less suitable for the intended use. After filling, sealing shall be performed in a manner that will maintain the integrity of the product during the dating period. In addition, final containers and closures for products intended for use by injection shall be sterile and free from pyrogens. Except as otherwise provided in the regulations of this subchapter, final containers for products intended for use by injection shall be colorless and sufficiently transparent to permit visual examination of the contents under normal light. As soon as possible after filling final containers shall be labeled as prescribed in § 610.60 et seq. of this chapter, except that final containers may be stored without such prescribed labeling provided they are stored in a sealed receptacle labeled both inside and outside with at least the name of the product, the lot number, and the filling identification.

[38 FR 32048, Nov. 20, 1973, as amended at 41 FR 10428, Mar. 11, 1976; 49 FR 23833, June 8, 1984; 55 FR 11013, Mar. 26, 1990]

## 21 CFR PART 820 - QUALITY SYSTEM REGULATION (01 April 2003)

### **Subpart G--Production and Process Controls**

#### **21 CFR 820.70 Production and process controls. (f) Buildings.**

VIP ID: 5809

Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mixups, and assure orderly handling.

### **Subpart G--Production and Process Controls**

#### **21 CFR 820.70 Production and process controls. (g) Equipment.**

VIP ID: 5810

Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.

### **Subpart G--Production and Process Controls**

#### **21 CFR 820.70 Production and process controls. (g) (1) Maintenance schedule.**

VIP ID: 5811

Each manufacturer shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented.

### **Subpart G--Production and Process Controls**

#### **21 CFR 820.70 Production and process controls. (g) (3) Adjustment.**

VIP ID: 5813

Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.

## CDER 05/01/87 GUIDELINE ON GENERAL PRINCIPLES OF PROCESS VALIDATION May, 1987 (Reprinted February 1993)

### VIII. ELEMENTS OF PROCESS VALIDATION

#### A. Prospective Validation 1. Equipment and Process - a. Equipment: Installation Qualification (para 5)

ViP ID: 854

Once the equipment configuration and performance characteristics are established and qualified, they should be documented. The installation qualification should include a review of pertinent maintenance procedures, repair parts lists, and calibration methods for each piece of equipment. The objective is to assure that all repairs can be performed in such a way that will not affect the characteristics of material processed after the repair. In addition, special post-repair cleaning and calibration requirements should be developed to prevent inadvertent manufacture of non-conforming product. Planning during the qualification phase can prevent confusion during emergency repairs which could lead to use of the wrong replacement part.

### VIII. ELEMENTS OF PROCESS VALIDATION

#### A. Prospective Validation 3. Documentation (para 2)

ViP ID: 871

For routine production, it is important to adequately record process details (e.g., time, temperature, equipment used) and to record any changes which have occurred. A maintenance log can be useful in performing failure investigations concerning a specific manufacturing lot. Validation data (along with specific test data) may also determine expected variance in product or equipment characteristics.

## COMMISSION DIRECTIVE 2003/94/EC OF 8 OCTOBER 2003 LAYING DOWN THE PRINCIPLES AND GUIDELINES OF GOOD MANUFACTURING PRACTICE IN RESPECT OF MEDICINAL PRODUCTS FOR HUMAN USE AND INVESTIGATIONAL MEDICINAL PRODUCTS FOR HUMAN USE

### Article 8

#### Premises and equipment 1

ViP ID: 67320

Premises and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the intended operations.

### Article 8

#### Premises and equipment 2

ViP ID: 67330

Premises and manufacturing equipment shall be laid out, designed and operated in such a way as to minimise the risk of error and to permit effective cleaning and maintenance in order to avoid contamination, cross contamination and, in general, any adverse effect on the quality of the product.

**COMMISSION DIRECTIVE 91/356/EEC - PRINCIPLES AND GUIDELINES OF  
GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS FOR  
HUMAN USE  
(June, 1991) - SUPERSEDED BY 2003/94/EC!!**

**Chapter II**

**Principles and Guidelines of Good Manufacturing Practice Article 8 - Premises and equipment 1.**

VIP ID: 777

Premises and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the intended operations.

**Chapter II**

**Principles and Guidelines of Good Manufacturing Practice Article 8 - Premises and equipment 2.**

VIP ID: 778

Lay out, design and operation must aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid contamination, cross contamination and, in general, any adverse effect on the quality of the product.