



# Current GMP Guidelines

By Dr. Abha Doshi



## Introduction

- **GMP** is a system for ensuring that products are consistently produced and controlled according to the quality standards.
- It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.
- It is designed to ensure that mistakes do not occur again.



## Introduction

- The quality cannot be tested into a batch of products but must be built into each batch of product during all stages of the manufacturing process.
- There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process.





## Introduction



# It could have been totally avoided!

By adopting



cGMP

❖ Metal contamination

❖ Wire inside the tablet

WHERE?

▪ From source

▪ From material API / excipient

▪ From the sifter

▪ From compression M/C

### WHAT ARE THOSE cGMP GUIDELINES?

#### 100% security sifting

- Passing through 30 mesh for fine powder – 100 mesh
- Magnetic grills at the sifter outlet.

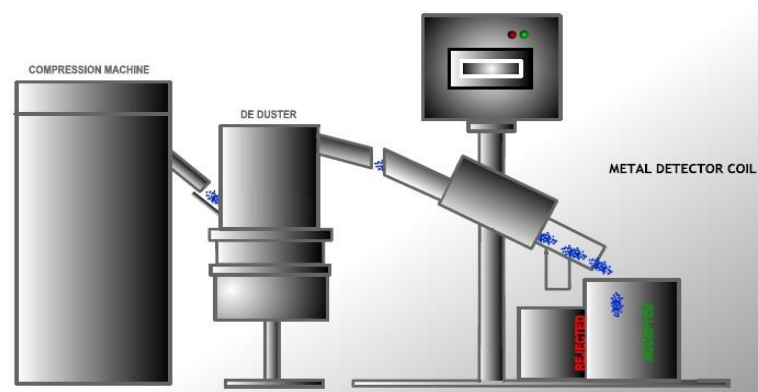


### WHAT ARE THOSE cGMP GUIDELINES?

#### Metallic contamination during compression

##### cGMP practice

- Metal detector in compression machine chute
- Any metallic piece of 0.1 mm size is detected → tablet discarded



### WHAT ARE THOSE cGMP GUIDELINES?

#### Metal detector can be installed in

- Tablet compression M/C
- Capsule filling M/C
- Dry syrup filling M/C
- Liquid oral filling
- Vial filling

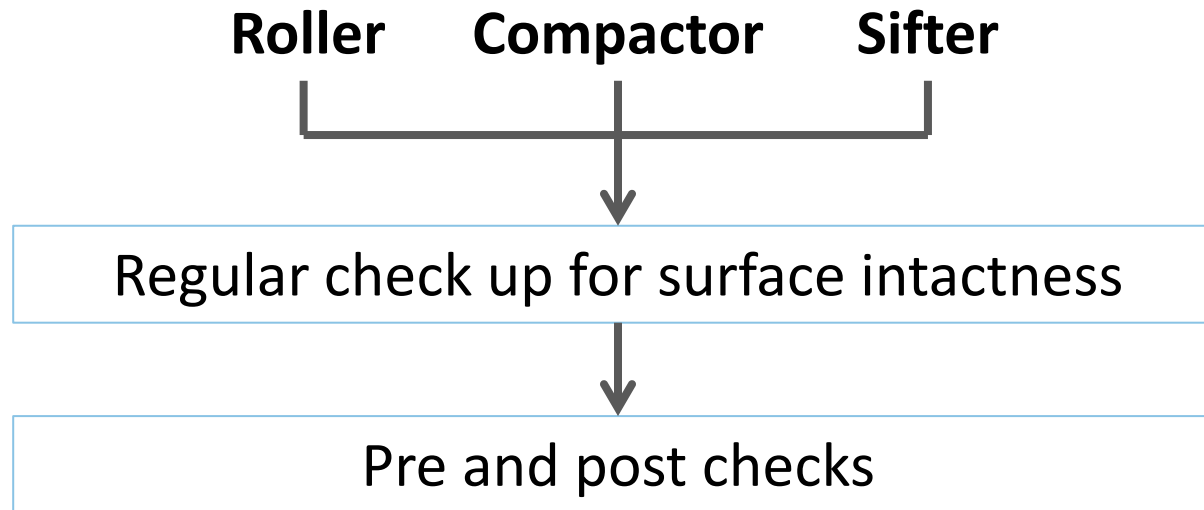


After filling,  
before capping





### WHAT ARE THOSE cGMP GUIDELINES?



## Introduction



### GMP Guidelines

- **Good Manufacturing Practices (GMP)** are the practices required to confirm the guidelines recommended by agencies that control **authorization** and **licensing** for manufacture and sale of food, drug products and active pharmaceutical products.
- These guidelines provide minimum requirements that a pharmaceutical or food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public.

## Introduction



- **GMP** is a common term.
- **cGMP** is a unique term to define most recent guidelines with improvement and additions.

## Introduction

- **GMP** regulations given by the **US FDA** under the authority of Federal Food, Drug and Cosmetic Act.
- As per the current good manufacturing practice process validation (updated) 1976 onwards :-



GMP



cGMP

## Introduction

**TITLE 21** of the **Code of Federal Regulation (CFR)** contains most regulations pertaining to food and drugs.

### 21 CODE OF FEDERAL REGULATIONS

#### Part 210

Current good manufacturing practices in manufacturing process is packing and holding of drug.

#### Part 211

Current **GMP** for finished pharmaceuticals.

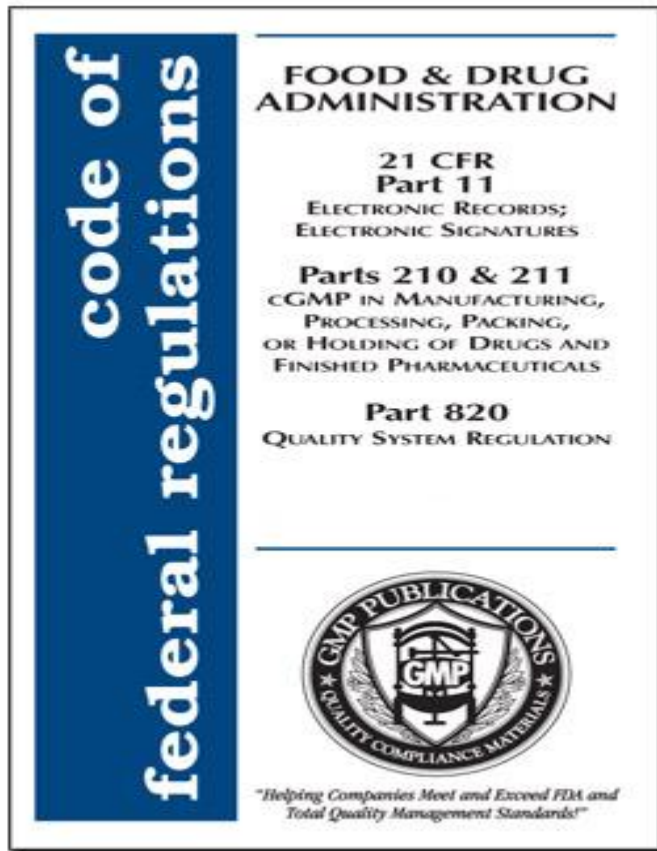


## Introduction

- By saying that any company employs **cGMP**- it indicates that they are following **21CFR 210** and **211** and no other.
- The office of compliance division of manufacturing and product quality web page provides link to in-process change in **cGMP** regulations announced in federal register.



## Introduction



- The FDA regulations are printed in **TITLE 21** (21 CFR).
- In addition, the FDA and other government agencies publish new regulations and proposals in the federal register throughout the year.
- Books on 21 CFR can be purchased from US government printing office.

### CODE OF FEDERAL REGULATION (CFR) TITLE 21



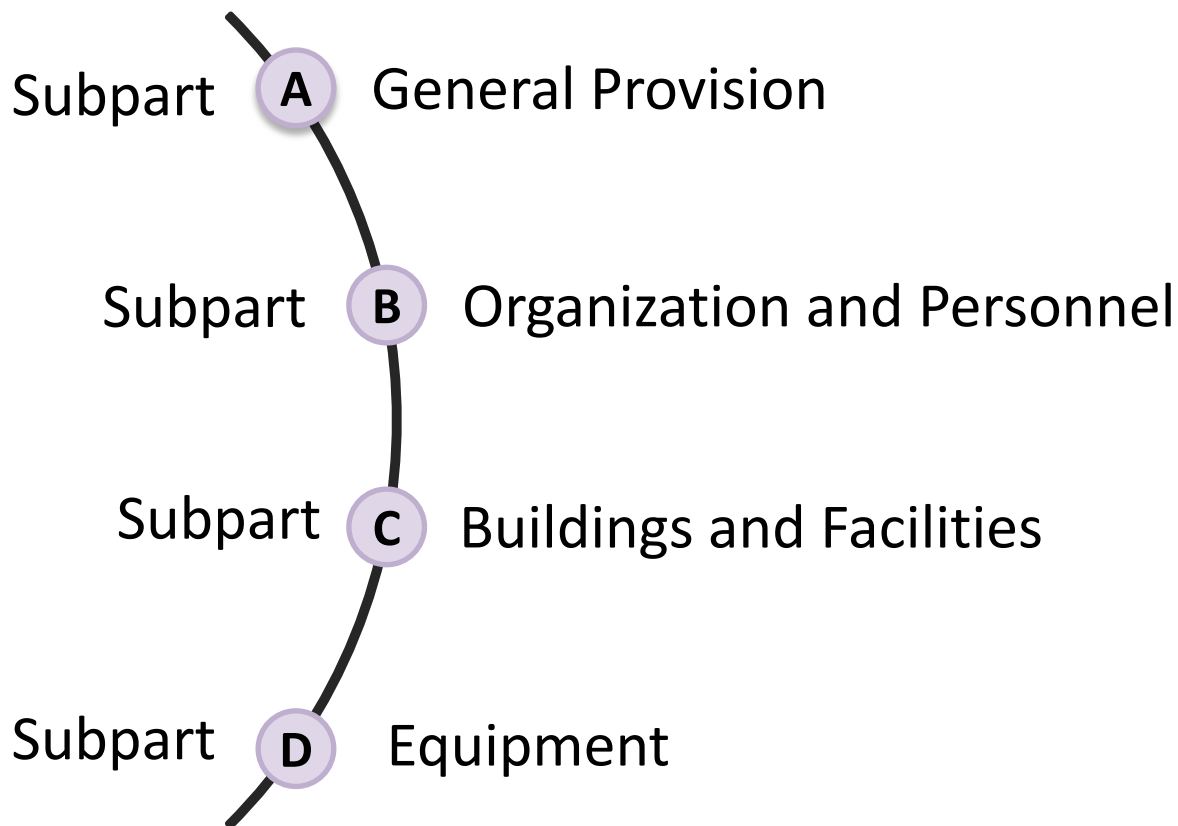
# 21



- Title 21, code of federal regulation (21 CFR) is updated on April 1<sup>st</sup> of each year.
- The current edition contains nine volumes and is printed in paper back books.

### Part 211

Current good manufacturing practices for finished pharmaceuticals.



### Part 211

Current good manufacturing practices for finished pharmaceuticals.

- Subpart **E** Control of components and drug product containers and closures
- Subpart **F** Production and process controls
- Subpart **G** Packaging and Labelling Control
- Subpart **H** Holding and Distribution



### Part 211

Current good manufacturing practices for finished pharmaceuticals.

Subpart **I** Laboratory Control

Subpart **J** Records and reports

Subpart **K** Returned and Salvaged Drug Products

## Introduction

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
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SUBCHAPTER C--DRUGS: GENERAL

PART 211 CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart A--General Provisions

- § 211.1 - Scope.
- § 211.3 - Definitions.

Subpart B--Organization and Personnel

- § 211.22 - Responsibilities of quality control unit.
- § 211.25 - Personnel qualifications.
- § 211.28 - Personnel responsibilities.
- § 211.34 - Consultants.

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.
- § 211.68 - Automatic, mechanical, and electronic equipment.
- § 211.72 - Filters.

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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.

§ 211.137 - Expiration dating.

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**Subpart H--Holding and Distribution**

§ 211.142 - Warehousing procedures.

§ 211.150 - Distribution procedures.

**Subpart I--Laboratory Controls**

§ 211.160 - General requirements.

§ 211.165 - Testing and release for distribution.

§ 211.166 - Stability testing.

§ 211.167 - Special testing requirements.

§ 211.170 - Reserve samples.

§ 211.173 - Laboratory animals.

§ 211.176 - Penicillin contamination.

**Subpart J--Records and Reports**

§ 211.180 - General requirements.

§ 211.182 - Equipment cleaning and use log.

§ 211.184 - Component, drug product container, closure, and labeling records.

§ 211.186 - Master production and control records.

§ 211.188 - Batch production and control records.

§ 211.192 - Production record review.

§ 211.194 - Laboratory records.

§ 211.196 - Distribution records.

§ 211.198 - Complaint files.

**Subpart K--Returned and Salvaged Drug Products**

§ 211.204 - Returned drug products.

§ 211.208 - Drug product salvaging.

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#### Subpart C--Buildings and Facilities

#### Sec. 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 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;



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Subpart C – Building and facilities

## **SEC. 211.42 – DESIGN AND CONSTRUCTION FEATURES**

Beta lactam antibiotics such as **penicillin, cephalosporin** and **penems** : separate manufacturing areas

Separate or defined areas for the manufacture and processing of non penicillin beta lactam products to prevent contamination

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## **SEC. 211.42 – DESIGN AND CONSTRUCTION FEATURES**

**At the time of designing and construction of the premises:**

- Preferably separate blocks for penicillin and non penicillin products.

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- Each block should be like a one factory.

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- No movement of workers from one block to another block.

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##### Subpart C--Buildings and Facilities

#### Sec. 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.

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## **SEC. 211.46 – VENTILATION, AIR FILTRATION, AIR HEATING AND COOLING.**

- Previously corridors were not defined areas
- Air bleeding from corridors
- Process corridors
  - Clean air
  - Class 1,00,000 - minimum requirement
  - Positive pressure

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## **SEC. 211.46 – VENTILATION, AIR FILTRATION, AIR HEATING AND COOLING.**

- Air locks  
Bubble locks  
Pressurized with respect to adjacent area
- Process area and adjacent area → classified
- Ventilation  
Oral formulation area → 10 air change  
Parenterals formulation area → 20 air change

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#### Subpart C--Buildings and Facilities

#### Sec. 211.50 - Sewage and refuse

Sewage, trash, and other refuse in and from the building and immediate premises shall be disposed of in a safe and sanitary manner.



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## **SEC. 211.50 – SEWAGE AND REFUSE**

Air outlet in the environment



Air should be passed through 0.22  $\mu\text{m}$   
double HEPA filter

- For preventing contamination
- For the healthy environment

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## **SEC. 211.50 – SEWAGE AND REFUSE**

For decontamination of penicillin and  
cephalosporin



Treatment with 2% NaOH solution

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## **SEC. 211.50 – SEWAGE AND REFUSE**

In other cases

Drug powder → converted into slurry



Incinerator



Converted to Ash



Ashes buried in the pits

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#### Subpart D--Equipment

### Sec. 211.67 - Equipment cleaning and maintenance

(a) Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized 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.

(b) 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.

(c) Records shall be kept of maintenance, cleaning, sanitizing, and inspection as specified in 211.180 and 211.182.

[43 FR 45077, Sept. 29, 1978, as amended at 73 FR 51931, Sept. 8, 2008]

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Subpart D – Equipment

## **SEC. 211.67 – EQUIPMENT CLEANING AND MAINTENANCE**

### **Clean Down Validation**

Cleaning procedure → Validated

- Pressurized hot water guns are used → 50°-60°C hot water
- The testing is done on worst molecule  
i.e - Having low aqueous solubility  
- Very potent drug

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## **SEC. 211.67 – EQUIPMENT CLEANING AND MAINTENANCE**

### **Clean Down Validation**

- Standardization is done with respect to :
  - Volume of water
  - Time
  - Machine
  - Surface area of contact
  - Pressure of water
  - Temperature



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## **SEC. 211.67 – EQUIPMENT CLEANING AND MAINTENANCE**

Process is validated



No need to wait for the result of residue of drug in the rinse water



(Limit of 5 PPM)

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#### Subpart G--Packaging and Labeling Control

#### Sec. 211.130 - Packaging and labeling operations

There shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products; such written procedures shall be followed. These procedures shall incorporate the following features:

- (a) Prevention of mixups and cross-contamination by physical or spatial separation from operations on other drug products.
- (b) Identification and handling of filled drug product containers that are set aside and held in unlabeled condition for future labeling operations to preclude mislabeling of individual containers, lots, or portions of lots. Identification need not be applied to each individual container but shall be sufficient to determine name, strength, quantity of contents, and lot or control number of each container.
- (c) Identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch.
- (d) Examination of packaging and labeling materials for suitability and correctness before packaging operations, and documentation of such examination in the batch production record.
- (e) Inspection of the packaging and labeling facilities immediately before use to assure that all drug products have been removed from previous operations. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection shall be documented in the batch production records.

[43 FR 45077, Sept. 29, 1978, as amended at 58 FR 41354, Aug. 3, 1993]

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Subpart G – Packaging and labelling control

## **SEC. 211.130 - PACKAGING AND LABELING OPERATIONS**

- Accountability of all packaging materials.
- Systems to ensure – printed labels are not mixed.
- Electronic readers are employed
- Pharma codes on all printed materials
- Auto reading – Auto rejection
- Roll labels are used – less chance of mix ups

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#### Subpart I--Laboratory Controls

#### Sec. 211.176 - Penicillin contamination

If a reasonable possibility exists that a non-penicillin drug product has been exposed to cross-contamination with penicillin, the non-penicillin drug product shall be tested for the presence of penicillin. Such drug product shall not be marketed if detectable levels are found when tested according to procedures specified in 'Procedures for Detecting and Measuring Penicillin Contamination in Drugs,' which is incorporated by reference. Copies are available from the Division of Research and Testing (HFD-470), Center for Drug Evaluation and Research, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

[43 FR 45077, Sept. 29, 1978, as amended at 47 FR 9396, Mar. 5, 1982; 50 FR 8996, Mar. 6, 1985; 55 FR 11577, Mar. 29, 1990; 66 FR 56035, Nov. 6, 2001; 69 FR 18803, Apr. 9, 2004]

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Subpart I – Laboratory control

## SEC. 211.176 – PENICILLIN CONTAMINATION

### Penicillin / Semi synthetic Penicillin

Testing of non – penicillin products for traces of penicillin or cephalosporin contamination



Sophisticated test methodology required

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## SEC. 211.176 – PENICILLIN CONTAMINATION

### Penicillin / Semi synthetic Penicillin

**Air sample test** – should be reported in volume of air

Surface  
testing

Should be capable of  
reflecting true value of  
contamination

Valid swab sampling  
technique required



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#### Subpart J--Records and Reports

#### Sec. 211.180 – General requirement

(a) Any production, control, or distribution record that is required to be maintained in compliance with this part and is specifically associated with a batch of a drug product shall be retained for at least 1 year after the expiration date of the batch or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under 211.137, 3 years after distribution of the batch.

(b) Records shall be maintained for all components, drug product containers, closures, and labeling for at least 1 year after the expiration date or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under 211.137, 3 years after distribution of the last lot of drug product incorporating the component or using the container, closure, or labeling.

(c) All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph.

(d) Records required under this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. Where reduction techniques, such as microfilming, are used, suitable reader and photocopying equipment shall be readily available.

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Subpart J – Records and Reports

## SEC. 211.180 – GENERAL REQUIREMENTS

- Automatic machine/ equipments
- Computerized
- Results are recorded
- Maintaining data online
  - Online Documentation



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## SEC. 211.180 – GENERAL REQUIREMENTS

- Environmental control :
  - Temperature
  - Pressure differential
  - RHAutomatically recorded
  
- Data integrity maintained



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## SEC. 211.180 – GENERAL REQUIREMENTS

### Data Integrity

**Data integrity** refers to maintaining and assuring the accuracy and consistency of data over the entire data cycle.



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Subpart J – Records and Reports

## SEC. 211.180 – GENERAL REQUIREMENTS

### Data Integrity

- Governance system should ensure data integrity and traceability.
- System should be designed in a way which encourages compliance with the principle of contemporary record keeping.



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Subpart J – Records and Reports

## SEC. 211.180 – GENERAL REQUIREMENTS

### Data Integrity

#### Example

- Access to clocks for recording timed events

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- Accessibility of batch records at locations where activities take place

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- Automated data capture or printers attached to equipment



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Thank You

