Current Good Manufacturing Practices and Current Good Compounding Practices

What are cGMPs

What are cGMPs

Regulations are established by the Food and Drug Administration **(FDA)** to ensure that **minimum** standards are met for drug product quality in the **United States**

OR

Rules set up by the FDA that drug manufacturers needs to follow in order to ensure that a **safe and effective** product is manufactured

cGMP

Code of Federal Regulations (CFR)

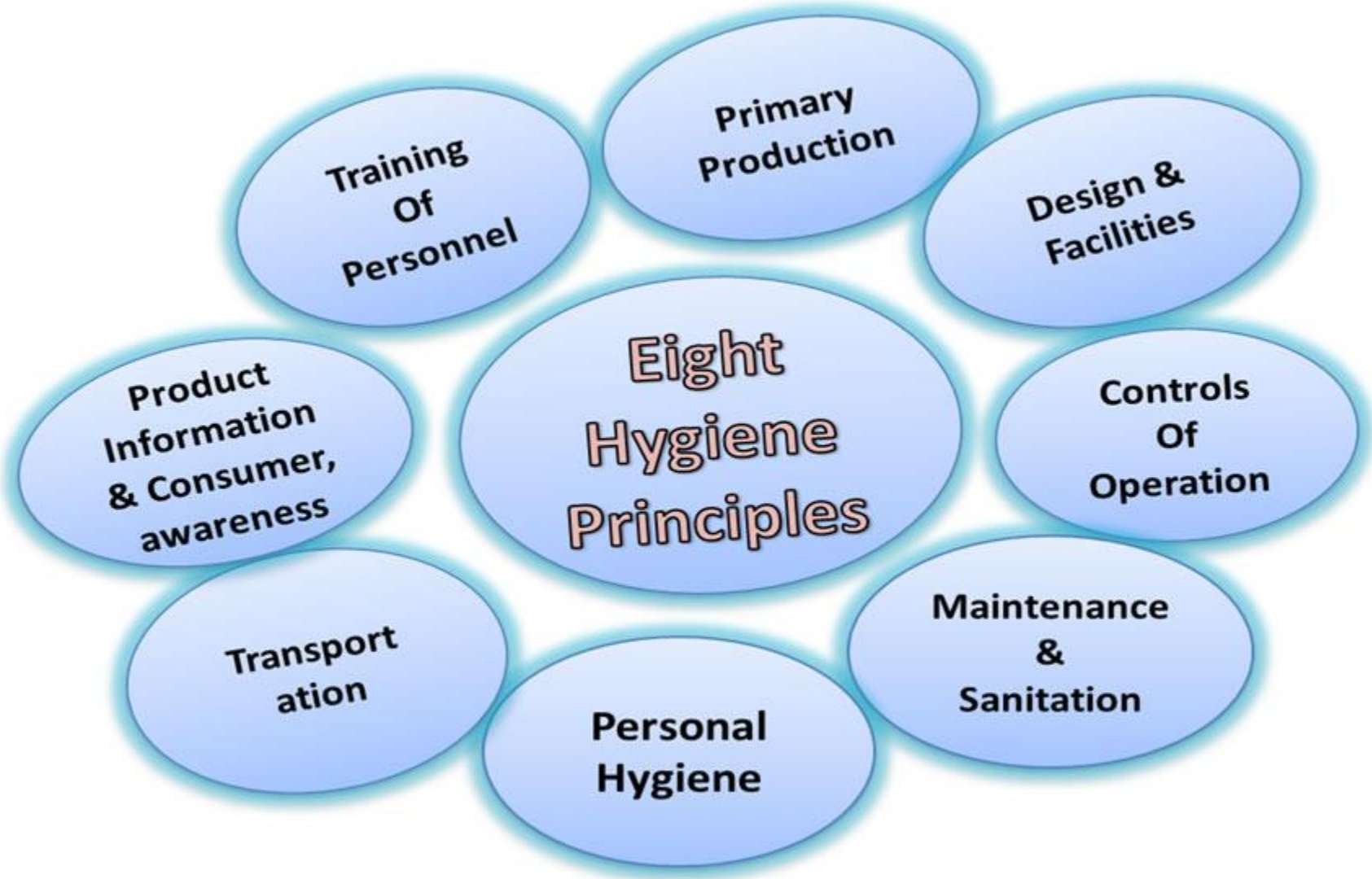
Finished Pharmaceuticals

Biologic products

Medicated articles

Medical devices

GMP


Eight Hygiene Principles
Primary Production
Design & Facilities
Controls Of Operation
Maintenance & Sanitation
Personal Hygiene
Transport ation
Product Information & Consumer, awareness
Training Of Personnel

GMP

GMP

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C--DRUGS: GENERAL

PART 211 CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211

The GMP Institute was established Ten Principles of cGMP

Principle1: Writing detailed step-by-step procedures that provide a roadmap for controlled and consistent performance

Principle2 : Carefully following written procedures to prevent contamination, mix-ups and errors

Importance of Written Procedures

Procedures should be
Clear , Concise and Logical

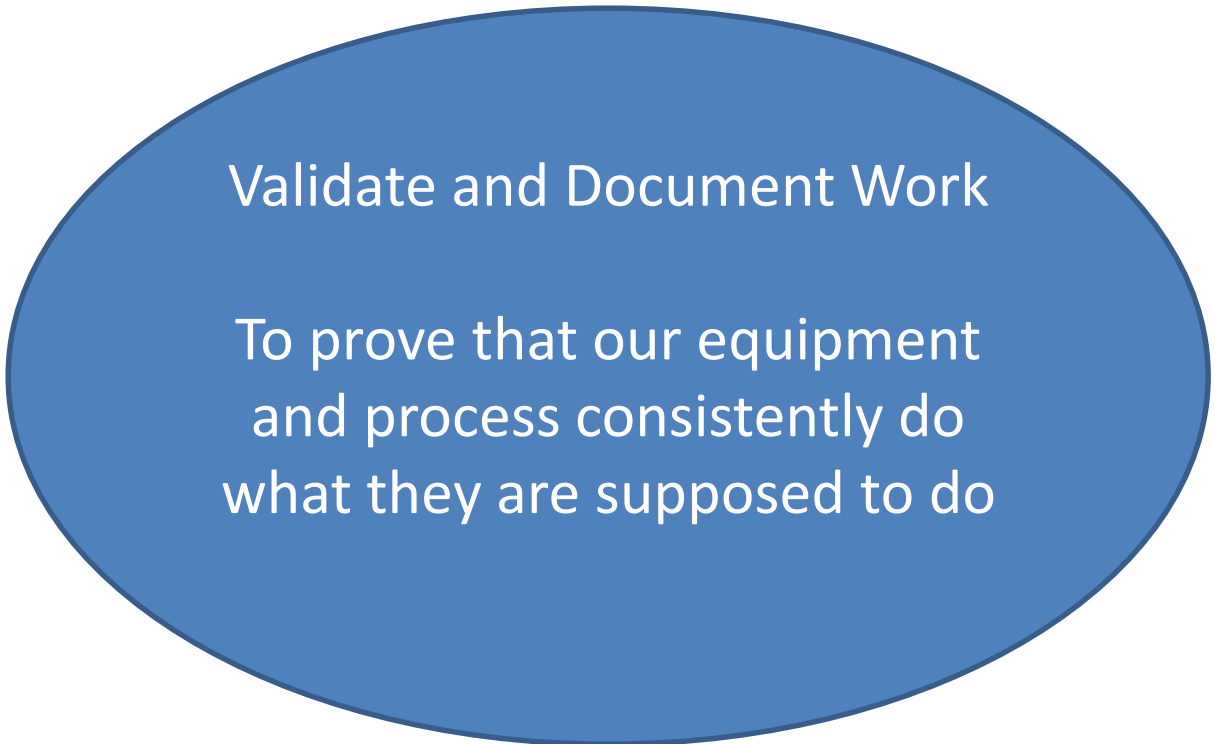
Importance of Written Procedures

Taking shortcuts may save time or make the task easier, but you **should never** deviate from a written procedure without the approval of a supervisor or Quality Department

The GMP Institute has established Ten Principles of cGMP

Principle3 : Promptly and accurately documenting work for compliance and traceability

Principle 4 : Proving that systems do what they are designed to do by validating



The GMP Institute has established Ten Principles of cGMP

Principle 5 : Develop a good design for the facility and the equipment from the beginning

Principle 6 : Properly maintaining facilities and equipment

Design , construction and maintenance of the facility and equipment

A Logical and well planning layout will improve productivity.

Remove unnecessary traffic in the production area

Segregate materials , products, and their components to minimize the confusion and potential mix-ups and errors

It is important to control :

Air, Water, Lighting, Ventilation, Temperature and RH

The GMP Institute has established Ten Principles of cGMP

Principle7 : Clearly defining, developing and demonstrating job competence

GMP makes for Competent Employees

Training: include basic training on the theory and practice of GMP as well as specific training relative to their role

Companies need people who know to do the job right the first time , every time

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Principle 8 : Protecting products against contamination by making cleanliness a continual habit

Practice good Hygiene

- Health examinations
- *Written procedures and instructions - to wash hands before entering production areas*
- Direct contact between product, raw materials and operator *Should be avoided*
- Protection of product from contamination:
  - ↗*Clean clothes appropriate to personnel activities*
  - ↗*Including hair covering (e.g. caps)*
- Check change rooms/changing facilities
- Smoking, eating and drinking not allowed in production areas, laboratories and storage areas
- No chewing (e.g. gum), or keeping food or drinks allowed
- No plants kept inside these areas
- Rest and refreshment areas should be separate from manufacturing and

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Principle 9: Building quality into products by.

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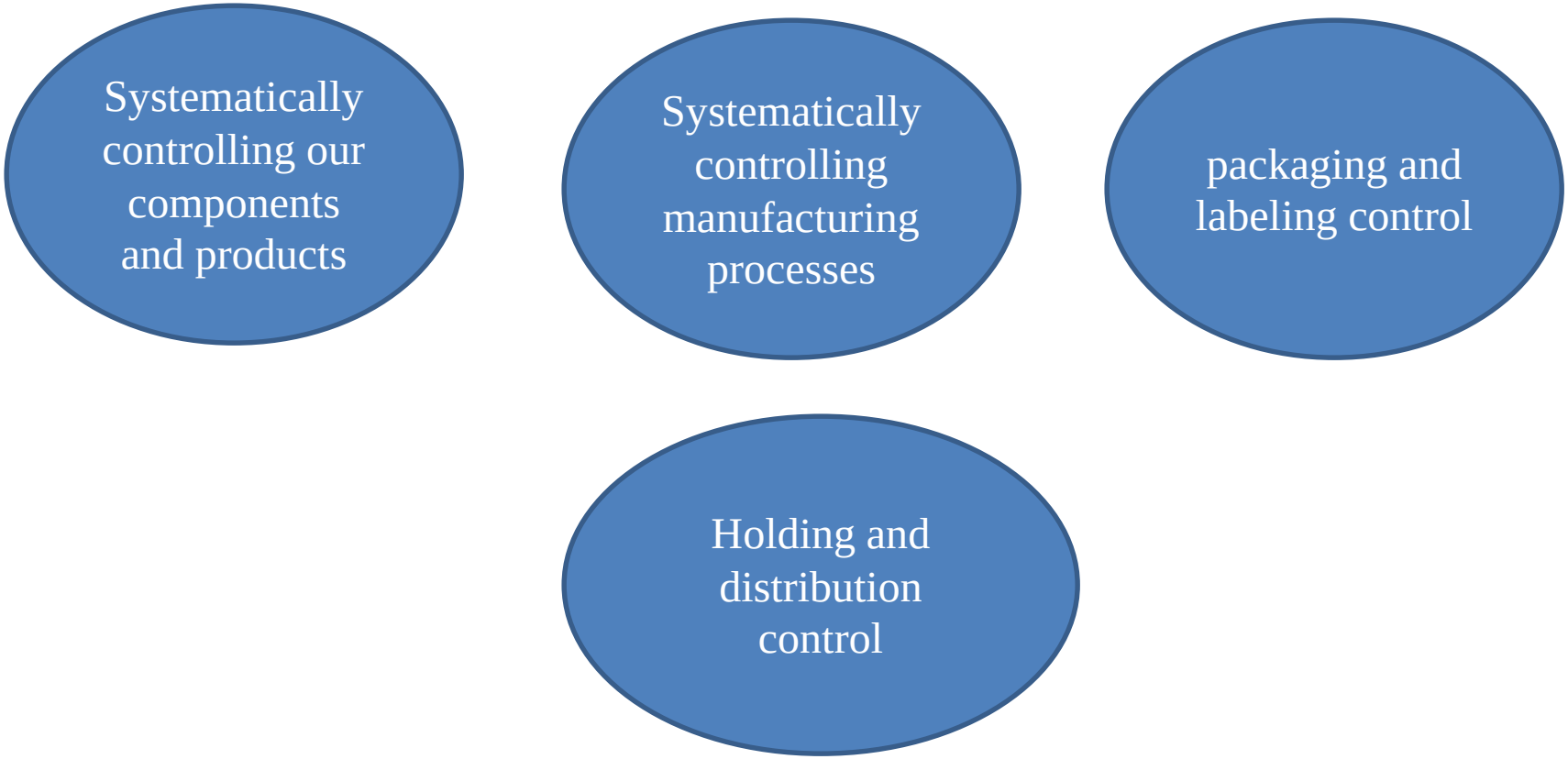

The GMP Institute has established Ten Principles of cGMP

Principle 10 : Conducting planned and periodic audits for compliance and performance.

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

- **Subpart A--General Provisions**
- **Subpart B--Organization and Personnel**
- **Subpart C--Buildings and Facilities**
- **Subpart D—Equipment**
- **Subpart E--Control of Components and Drug Product Containers and Closures**
- **Subpart F--Production and Process Controls**

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

- Subpart G--Packaging and Labeling Control
- Subpart H--Holding and Distribution
- Subpart I--Laboratory Controls
- Subpart J--Records and Reports
- Subpart K--Returned and Salvaged Drug Products

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

- Active ingredient or active pharmaceutical ingredient (API): Any component that is intended to furnish pharmacologic activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure or function of the body of man or other animals.

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

- **Batch**: A specific quantity of a drug of uniform specified quality produced according to a single manufacturing order during the same cycle of manufacture

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

- **Lot**: A batch or any portion of a batch having uniform specified quality and a distinctive identifying lot number.
- **Lot number, control number, or batch number**: Any distinctive combination of letters, numbers, or symbols from which the complete history of the manufacture, processing, packaging, holding, and distribution of a batch or lot of a drug product may be determined.

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- **Certification**: Documented testimony by qualified authorities that a system qualification, calibration, validation, or revalidation has been performed appropriately and that the results are acceptable.
- **Compliance**: Determination through inspection of the extent to which a manufacturer is acting in accordance with prescribed regulations, standards, and practices.

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- **Component**: Any ingredient used in the manufacture of a drug product, including those that may not be present in the finished product.
- **Inactive ingredient**: Any component other than the active ingredients in a drug product
- **Drug product:** A finished form that contains an active drug and inactive ingredients. The term may also include a form that does not contain an active ingredient, such as a placebo.

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- **Master record**: Record containing the formulation, specifications, manufacturing procedures, quality assurance requirements, and labeling of a finished product

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- **Quality assurance**: Provision to all concerned the evidence needed to establish confidence that the activities relating to quality are being performed adequately.
- **Quality audit**: A documented activity performed in accordance with established procedures on a planned and periodic basis to verify compliance with the procedures to ensure quality.

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- **Quality control**: The regulatory process through which industry measures actual quality performance, compares it with standards, and acts on the difference.
- **Quality control unit**: An organizational element designated by a firm to be responsible for the duties relating to quality control

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- **Quarantine**: An area that is marked, designated, or set aside for the holding of incoming components prior to acceptance testing and qualification for use.

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- **Reprocessing**: The activity whereby the finished product or any of its components is recycled through all or part of the manufacturing process.
- **Strength**: The concentration of the drug substance per unit dose or volume

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

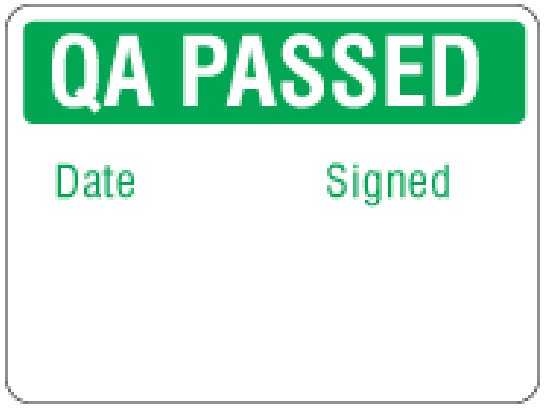
Subpart A--General Provisions

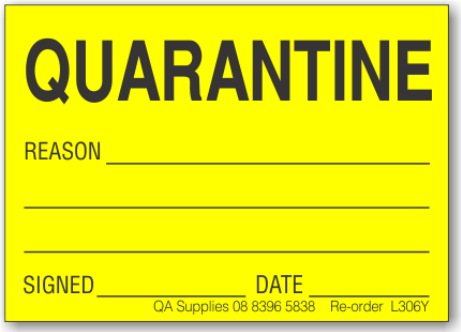
The regulations in this part contain the **minimum** current good manufacturing practice for preparation of drug products (excluding positron emission tomography drugs) for administration to humans or animals

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart B--Organization and Personnel

- Responsibilities of quality control unit.
- Personnel qualifications.
- Personnel responsibilities.
- Consultants.





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Subpart B--Organization and Personnel

- **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

(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.

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Subpart B--Organization and Personnel

- 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.

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

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart B--Organization and Personnel

- Personnel responsibilities.

(a) Personnel engaged in the manufacture, processing, packing, or holding of a drug product **shall** wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination.

(b) Personnel shall practice good sanitation and health habits.

(c) Only personnel authorized by supervisory personnel **shall** enter those areas of the buildings and facilities designated as limited-access areas.

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Subpart B--Organization and Personnel

- Consultants.

Consultants advising on the manufacture, processing, packing, or holding of drug products **shall have** sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart C--Buildings and Facilities

- Design and construction features.

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.

shall have adequate space

- Lighting.
- Ventilation, air filtration, air heating and cooling.
- Plumbing.
- Sewage and refuse.
- Washing and toilet facilities.
- Sanitation.
- Maintenance.

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart D—Equipment

- Equipment design, size, and location.
- Equipment construction.

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

-Equipment cleaning and maintenance.

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

- Automatic, mechanical, and electronic equipment.
- Filters.

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.

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart E--Control of Components and Drug

- Receipt and storage of untested components, drug product containers, and closures.
- Testing and approval or rejection of components, drug product containers, and closures.
- Use of approved components, drug product containers, and closures.
- Retesting of approved components, drug product containers, and closures.
- Rejected components, drug product containers, and closures.
- Drug product containers and closures.

The component is assigned a control number that identifies both the component and the intended product.

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Subpart F--Production and Process Controls

- Written procedures; deviations.
- Charge-in of components.
- Calculation of yield.
- Equipment identification.
- Sampling and testing of in-process materials and drug products.
- Time limitations on production.
- Control of microbiological contamination.
- Reprocessing.

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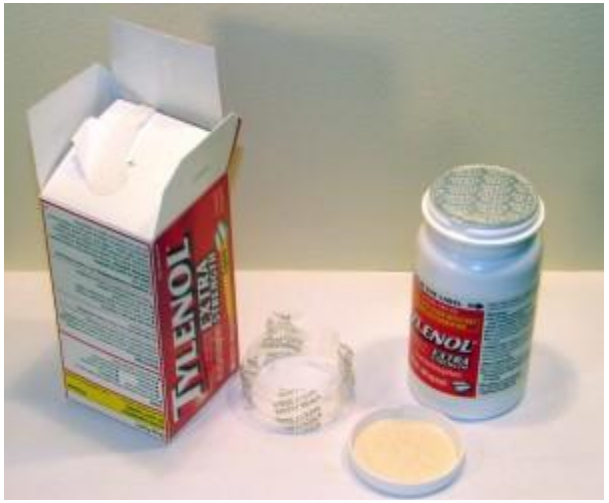
Subpart G--Packaging and Labeling Control

- Materials examination and usage criteria.
- Labeling issuance.
- Packaging and labeling operations.
- Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.
- Drug product inspection.
- Expiration dating.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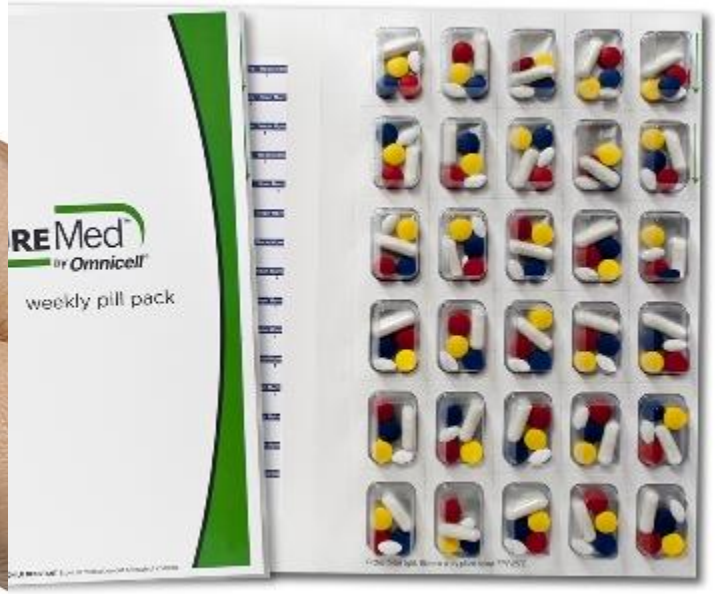
REMed
by Omnicell
weekly pill pack

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart H--Holding and Distribution

- Warehousing procedures.
- Distribution procedures.

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Subpart I--Laboratory Controls

- General requirements.
- Testing and release for distribution.
- Stability testing.
- Special testing requirements.
- Reserve samples.
- Laboratory animals.
- Penicillin contamination.

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart J--Records and Reports

- General requirements.
- Equipment cleaning and use log.
- Component, drug product container, closure, and labeling records.
- Master production and control records.
- Batch production and control records.
- Production record review.
- Laboratory records.
- Distribution records.
- Complaint files.

QUALITY RELATIONSHIP

Quality Management

Quality Assurance

G.M.P.

Quality Control