

Glisland® Training Series:

Good Manufacturing Practice

Glisland, Inc.

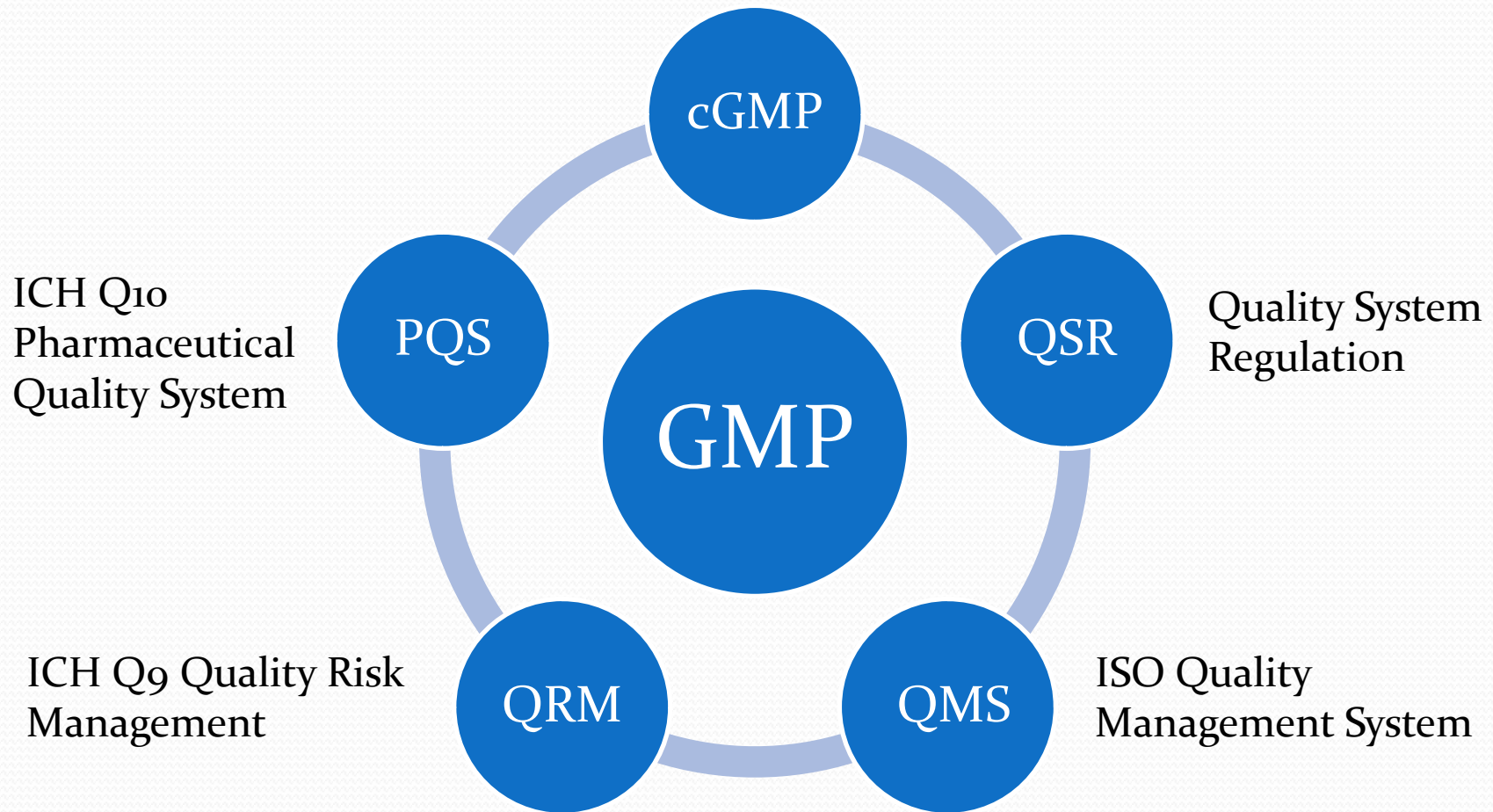
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Welcome to GMP World

Current Good Manufacturing Practice





Drug Related Laws

1. Pure Food and Drugs Act of 1906
2. Federal Food, Drug & Cosmetic Act of 1938
3. Durham-Humphrey Amendment of 1951
4. Kefauver-Harris Drug Amendments of 1962
5. Orphan Drug Act of 1983
6. Drug Price Competition and Patent Term Restoration Act of 1984
7. Prescription Drug User Fee Act of 1992
8. FDA Modernization Act of 1997
9. FDA Amendments Act of 2007

FDA GMP Regulations

1. 21 CFR Part 210 (General)
2. 21 CFR Part 211 (Finished pharmaceuticals)
3. 21 CFR Part 216 (Pharmacy compounding)
4. 21 CFR Part 225 (Medicated feeds)
5. 21 CFR Part 226 (Type A medicated articles)
6. 21CFR Part 600-680 (Biologics)
7. 21 CFR Part 1271 (Human cells, tissues, and cellular and tissue-based products (HCT/P's))

Website to download 21 CFR:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>



21 CFR Part 211 Components

1. Organization and Personnel
2. Buildings and Facilities
3. Equipment
4. Control of Components and Drug Product Containers and Closures
5. Production and Process Controls
6. Packaging and Labeling Control
7. Holding and Distribution
8. Laboratory Controls
9. Records and Reports
10. Returned and Salvaged Drug Products



-Organization and Personnel

1. Responsibilities of quality control unit

- a) Responsibility and authority
- b) Testing and approval or rejection
- c) Components, containers, closures, in-process materials, packaging materials, labeling, drug products, procedures, specifications

2. Personnel qualifications

- a) Education, training, experience
- b) cGMP training
- c) Adequate number



-Organization and Personnel

3. Personnel responsibilities

- a) Clean clothing, protective apparel
- b) Good sanitation and health habits
- c) Limited-access

4. Consultants

- a) Education, training, experience
- b) Name, address, qualifications, type of service



-Buildings and Facilities

1. Design and construction features

- a) Suitable size, facilitate cleaning, maintenance, and proper operations
- b) Adequate space to prevent mixups and contamination
- c) Special defined areas for operations to prevent contamination or mixups
- d) Separate facility for penicillin operations

2. Lighting

Adequate lighting in all areas



-Buildings and Facilities

3. **Ventilation, air filtration, air heating and cooling**
 - a) Adequate ventilation
 - b) Adequate control over air pressure, micro-organisms, dust, humidity, and temperature
 - c) Air filtration systems and exhaust systems to control contaminants
 - d) Separate air-handling systems for the manufacture, processing, and packing of penicillin



-Buildings and Facilities

4. Plumbing

- a) Continuous positive pressure for potable water supply
- b) EPA Primary Drinking Water Standards for potable water
- c) Prevent back-siphonage in drains

5. Sewage and refuse

Dispose in a safe and sanitary manner

6. Washing and toilet facilities

Hot and cold water, soap or detergent, air driers or single-service towels, and clean toilet facilities easily accessible to working areas



-Buildings and Facilities

7. Sanitation

- a) Free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals)
- b) Written procedures

8. Maintenance

Maintained in a good state of repair



-Equipment

1. **Equipment design, size, and location**

Appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.

2. **Equipment construction**

- a) Surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive
- b) No contamination from operation substances such as lubricants or coolants



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