CPGP PHARMACEUTICAL GMP PROFESSIONAL CERTIFICATION

Regulatory Agency Governance

A. Global Regulatory Framework

B. Regulations and Guidances

C. Mutual Recognition Agreements

D. Regulatory Inspections

E. Enforcement Actions

F. Regulatory Agency Reporting

- Post-marketing changes
- Regulatory reporting requirements
- Product surveillance

G. Site Master File (SMF), Validation Master Plan (VMP) and Drug Master File (DMF) and Site Reference File (SRF)

Quality Systems

A. Quality Management

B. Quality Unit (Site) Management

C. Risk Management

D. Training and Personnel Qualification

1. Needs analysis

2. Staff development requirements

E. Change Control and Management

1. Pre-change analysis

2. Post-change analysis

F. Investigations and Corrective and Preventive Action (CAPA)

1. Trigger events

2. Response actions

3. CAPA feedback and trending

G. Audits and Self-inspections

1. Audits processes and results

2. Audit follow-up

H. Documents and Records Management

1. GMP document system

2. Records

3. Record retention

I. Product Complaints and Adverse Event Reports

1. Product complaints

2. Adverse events

3. Event response

J. Product Trend Requirements

K. Supplier and Contractor Quality Management

1. Supplier quality systems

2. Supplier controls

3. Supplier evaluation

Laboratory Systems

A. Compendia (United States, Europe, and Japan)

1. Required vs. informational compendia

2. Marketing requirements vs. compendia

3. Compendial methods review

4. Compendial or non-compendial requirements review

5. Biological, microbiological, chemical, and physical test methods

B. Laboratory Investigations of Atypical Results

1. Test data

2. Atypical results

3. Instrument Management

4. Instrument controls

5. Instrument calibration

C. Specifications

1. Types of specifications

2. Test data and specifications

3. Specifications revision

D. Laboratory Record-keeping and Data Requirements

1. Record-keeping requirements

2. Record review

3. Certificates of analysis (COAs)

E. Laboratory Handling Controls

1. Sample handling

2. Reagents, solutions, and standards identification

3. Storage requirements

4. Stability Programs

5. Release tests vs. stability-indicating tests

6. Stability test data

7. Stability-point failure

F. Reserve Samples and Retains

Infrastructure: Facilities, Utilities, Equipment

A. Facilities

1. Buildings

2. Manufacture and storage environment

3. Facilities change control

B. Utilities

1. Water supply systems

2. Compressed air and gas systems

3. Utility design for production

4. Utilities design specifications

5. Utilities change control

C. Equipment

1. Equipment planning

2. Equipment layout

3. Equipment cleaning and maintenance

4. Equipment cleaning validation or verification

5. Equipment change control

D. Qualification and Validation

E. Maintenance and Metrology Systems

1. Maintenance procedures

2. Metrology change control

F. General Cleaning, Sanitization, and Sterilization Systems

1. Cleaning procedures

2. Sanitization procedures

3. Pest control

4. Sterilization processes

G. Automated or Computerized Systems

1. Validation procedures

2. Open and closed computerized systems

3. Configuration control 4. Security requirements

H. Business Continuity and Disaster Recovery Planning

1. Supply chain impact

2. Contingency plan

Sterile and Non-sterile Manufacturing Systems

A. Master Batch and Completed Batch Records

1. Required elements

2. Record processing requirements

B. Production Operations

1. Application factors

2. Utility requirements

3. Sanitization and protection

C. In-process Controls

1. In-process testing

2. Critical process parameters (CPPs)

3. Process capability studies

4. Specification limits

D. Dispensing and Weighing Controls

1. Staging areas

2. Dispensing materials

E. Requirements for Critical Unit Processes

1. Process parameters

2. Validation studies

3. Unit operations

4. Operating procedures

5. Re-evaluation and revalidation

6. Environmental

7. Environmental monitoring tools

F. Contamination and Cross-contamination

1. Sources

2. Risk mitigation

G. Reprocessed and Reworked Materials

1. Disposition process

2. Storage

Materials and Supply Chain Management

A. Receipt of Materials

1. Incoming materials

2. Inventory controls

B. Sampling Processes

1. Sampling plans

2. Sampling environment

3. Cleaning

C. Material Storage, Identification, and Rotation

1. Storage suitability

2. Storage labels

3. Stock rotation

4. Retest dates vs. expiration dates

5. Mix-up risk

D. Shipping and Distribution

1. Temperature-sensitive requirements

2. Special requirements

3. Report requirements

4. Supply chain security

E. Traceability and Sourcing

1. Traceability requirements

2. Biological agent requirements

3. Pedigree and sourcing requirements

F. Salvaged/Returned Goods and Destruction

1. Disposition

2. Destruction facilities and processes

3. Supplier evaluation

Filling, Packaging, Labeling

A. Filling Operations and Controls

1. Materials control

2. Filling equipment control

3. Contamination controls

4. Staged materials

5. Status labeling

B. Environmental Monitoring

C. In-process and Finished Goods Inspections

1. Inspections

2. Vision and detection systems

3. Defect characterizations

4. Equipment failure detection

D. Product Inspection

1. Staff evaluation

2. Inspector requirements

3. Automated inspection processes

E. Packaging Operations and Controls

1. Content protection

2. Qualification and maintenance of equipment

3. Line clearance operations

4. Quality check criteria

5. Cut-label procedures

6. Hand-applied label procedures

7. Packaging controls 8. Contamination controls

9. Tamper-evident packaging

F. Labeling Operations and Controls

1. Label printing in packaging

2. Quality of print used

3. Label changes

4. Label reconciliation

5. Unused labels

6. Label production

7. Access control

G. Filling and Packaging Records

1. Terms

2. Setup instructions

Product Development and Technology Transfer

A. Quality by Design Concepts

1. Critical quality attributes

2. Design space 3. Process analytical technology (PAT) tools

B. Phase-appropriate GMP Requirements

1. Product life cycle development

2. Development phases

3. Combination products

4. Clinical trials material

C. Raw Materials, Packaging, and Infrastructure for Product Development

D. New Product Development Studies and Reports

E. Scale-up and Transfer Activities

1. Development and validation principles

2. Technology transfer types

3. Successful technology transfer