GMP Basics Objectives

1. State the critical definitions of the pharmaceutical industry.
2. Describe the law as it applies to various critical functions.
3. State the history of cGMPs.
4. Describe the future goals and initiatives of the FDA.
5. Explain the types of FDA inspections.
6. Explain the legal consequences of cGMP non-compliance.
7. State the personnel requirements for working in plants.
8. State the value, origin and need to comply with procedures.
9. Describe the considerations for writing procedures.
10. Explain the role of quality assurance in managing procedures.
11. Explain the purpose of investigations.
12. Explain personal responsibilities in controlling contamination.
13. Explain how personal hygiene practices control contamination: Hygiene, clothing, restroom, and clean room practices.
14. Explain the role of cleaning procedures: SOPs, documentation, logs, and trash.
15. Explain the role of cleaning documentation practices.
16. Explain the rules for completing and correcting documents.
17. Demonstrate proper documentation practices.
18. Explain unacceptable documentation practices.
19. State the other areas where documentation is important to our GMP compliance.
20. Explain the importance of raw materials sources.
21. Describe the function and importance of specifications.
22. Describe the function and methods of quarantine.
23. Describe the use and method of sampling.
24. Describe the requirements for properly receiving materials.
25. Explain acceptance of raw materials by certificate of analysis.
26. Describe the role of lot numbers.
27. Describe the requirements for secondary containers.
28. Describe the requirements for testing and inspection of incoming materials.
29. Describe material controls methods.
30. Describe the product related problems with adulteration.
31. Explain First In First Out (FIFO).
32. Demonstrate yield calculation.
33. List the methods for proper handling raw materials.
34. Describe the value of online testing.
35. Describe the requirements for the control of labeling.
36. Explain the need for accountability of materials.
37. Describe the requirements for returned product. List the methods for proper handling of non-conforming materials.

Intermediate Objectives

1. Describe production material controls.
2. Describe processing controls.
3. Explain the use of sampling as a means to control processes.
4. Explain the use of online testing to control processes.
5. Explain how to use control charts.
6. Describe what to do when deviations occur.
7. Explain the requirements and role of documentation of production processes.
8. State the requirements for proper facility design.
9. Describe the requirements for a dedicated space.
10. Explain the controls and specifications for utilities.
11. Explain the value of proper housekeeping.
12. Explain the rationale for equipment design and selection.
13. Explain the requirements for appropriateness equipment use.
14. State the requirements for equipment cleaning.
15. State the requirements for equipment maintenance.
16. State the requirements for equipment documentation.
17. Explain the need for equipment identification.
18. Describe the requirements and process of calibration.
19. List the requirements for calibration documentation.
20. Explain the QA role in assuring a GMP compliant source for raw materials.
21. Describe the QA role in receiving materials.
22. Explain the QA role in sampling.
23. Describe the QA role in inspections.
24. Explain the QA role in handling nonconforming materials.
25. Describe the QA role in documentation review and archive.
26. Explain the QA role in audits and inspections.
27. Explain the QA role in recalls.
28. Explain the role of quality control.
29. Explain what we do with analytical results.
30. Describe the actions to take when presented with out of specification results.
31. Explain the process of conducting a deviation investigation.
32. Explain what we look for when reviewing a certificate of analysis.
33. Describe the requirements for laboratory notebooks and the associated review.
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Advanced Objectives

1. Describe the purpose of validating equipment and processes
2. Explain the different steps of validation; IQ, OQ, PQ, and PV
3. Explain the goals of validation documentation
4. Describe a validation protocol
5. Describe the different types of validation
6. State the requirements for cleaning validation
7. List the documentation requirements for validation.
8. Describe the goals of computer validation
9. Describe the hardware issues addressed in computer validation
10. Explain the concern of computer location
11. Describe the software issues addressed in computer validation
12. Explain the concern of computer operation
13. Describe the requirements for computer alarms
14. Describe the requirements for computer shutdowns
15. Describe the requirements for computer security
16. Describe the requirements of an electronic record and signature system
17. Explain the definition associated with electronic record and signatures
18. Describe the requirements for controls on open and closed systems
19. Explain the requirement for audit trails
20. State the requirement for training
21. List the issues associated with signatures
22. Describe the requirements for ID codes and passwords.
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### GMP Essentials Class

<table>
<thead>
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<td>• The FDA and GMPs</td>
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<td>2. Regulatory Inspections</td>
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<td>• Quality Systems Inspection Technique</td>
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<td>• Traditional Inspections</td>
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<td>3. Legal Consequences</td>
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<td>• Observation of Violation of GMPs</td>
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<td>• Fines</td>
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<td>• Imprisonment</td>
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</tbody>
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### People and Procedures

1. Organization and personnel
   - Organization chart
   - Personnel training
   - Training audit
   - Consultants and contractors
   - Staffing

2. Standard operating procedures
   - Defined
   - Quality Assurance responsibility
   - Title
   - General format
   - Writing guidelines
   - Writing, revisions, review, and approval
   - Review frequency
   - Activity: Writing Procedures
   - Activity: House Building

3. Investigations
   - Investigation overview
   - Deviation investigation
   - Investigation documentation
   - Returned product investigations
   - Complaint investigations
   - GMP wrap up activity
   - Change history
   - Printing instructions

### Contamination Control

1. Sources of contamination
   - Plant food rules
   - Live sources
   - Personal contamination rules
   - Contamination categories
   - Activity: Contamination Sources
   - Penicillin contamination

2. Personal hygiene
   - Aseptic or clean room activities
   - Rest rooms and hand washing
   - Clothing to be worn

### 3. Environmental monitoring
   - What gets sampled and tested
   - Sampling and testing issues
   - Major influences

### 4. Cleaning
   - Procedures
   - Level of equipment cleaning
   - Work space cleaning
   - Refuse and trash

### 5. Documentation
   - Major and minor equipment
   - Logs

### Documentation

1. Regulations
2. Documentation rules and practices
   - Completing documentation
   - Correcting documentation
   - Error descriptions
   - Unacceptable documentation practices
   - Fraud and falsification policy
   - Activity: Short Term Memory

3. Double checking
   - Specific examples
   - Options
   - Activity: Documentation Contribution

4. Required documentation
   - Major equipment logs
   - Component, drug product, container, closure and labeling records
   - Production documentation
   - Production record review
   - Quality control
   - Specifications
   - Receiving, storing, and distribution records
   - Returned drug products or complaint records

5. Other required documentation
   - Quarantine system
   - Sampling
   - First In First Out
   - Charge-in of active ingredients
   - On line testing
   - Calculation of yield
   - Destruction of unused labeling
   - Work space cleaning
   - Maintenance
   - Training and education
   - Investigations
   - Validation
   - Internal audits
   - Calibration
   - Documentation retention

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Materials
1. Regulations
   • Approving raw material suppliers
   • Supplier qualification program
   • Regular review of suppliers
2. Sourcing raw materials
   • Sources of specifications
   • Acceptable limits or ranges
   • Labels and labeling
3. Specifications
   • Approving raw material suppliers
   • Supplier qualification program
   • Regular review of suppliers
4. Quarantine system
   • Definitions
   • Purpose of the system
   • Quarantine components
   • Approved components
   • Rejected components
   • Experimental status
   • Dedicated areas
5. Sampling
   • Timing
   • Procedure practices - general
   • Procedure practices - specific
   • Container identification
   • Activity: Bead Sort
6. Receipt of materials
   • Inspection by warehouse
   • Receiving and storing
   • Receiving inspection
   • Testing
   • Material examination
   • Certificate of analysis
7. Identification of materials
   • Lot numbers
   • Expiration dates
   • Containerization labeling
   • Re-containerization
8. Contamination
   • Types of material adulteration
   • Chemical and physical contaminants
9. Material Controls
   • Material storage space
   • First In First Out
   • Charge-in of active ingredients
   • Amount of active ingredient
   • On line testing
   • Calculation of yield
   • Double checking
10. Labels and labeling
    • Packaging and labeling supplies
    • Labels and labeling examination
    • Activity: Product Labeling
    • Strict control over labeling supplies
    • Label accountability
    • Returned labeling stock
    • Destruction of labeling
11. Non-conforming materials
    • Purpose
    • Investigations
    • Returned product investigation

Production and Process Controls
1. Regulations
   • Identity, strength, quality, and purity
   • Planned deviations
   • Unplanned deviations
2. Procedures
   • Identity, strength, quality, and purity
   • Planned deviations
   • Unplanned deviations
3. Materials
   • Weighting of materials
   • Charge-in of active ingredients
   • Amount of active ingredient
   • Calculation of yield
   • Yield values
4. Equipment
   • Identification
   • Processing controls
5. Sampling
   • Statistical, random, or representative
   • Finished product testing
   • In-process testing
   • Control chart action signals
   • Activity: Sampling
6. Processing
   • Time limitations on production
   • On line testing
7. Contamination controls
   • Microbiological contamination
8. Reprocessing and rework
   • Guidelines
9. Documentation
   • Batch records
   • Retention times

Buildings and Facilities
1. Space Regulations
   • Adequate space
   • Sufficient space defined
   • Product flow
2. Designated Spaces
   • Manufacturing and storage space
   • Receiving inspection space
   • Storage environment
   • Laboratory space
   • Work in process (WIP)
   • Quarantine and reject space
   • Restricted or limited access
3. Utilities
   • Lighting
   • HVAC
   • Laminar flow
   • HEPA filters
   • Plumbing
   • Classes of water
   • Air breaks
   • Maintenance
4. Housekeeping
   • Washing and toilet facilities
   • Refuse and trash
   • Work space levels of cleaning
   • Pest control and suggestions
   • Facility design activity

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Equipment

1. Regulations
2. Design
   • Appropriate and suitable
   • Equipment selection
   • Blue prints of process
   • Control devices
3. Construction
   • Equipment materials of construction
   • Lubricants
4. Filters
   • Design and specifications
   • Fiber releasing
   • High Efficiency Particulate Air filters (HEPA Filters)
5. Use
   • Procedures
   • Training requirements
   • Training program structure
6. Cleaning
   • Levels of cleaning
   • Procedures
   • Equipment cleaning logs
7. Maintenance
   • Work and repair orders
   • Logs
8. Identification
   • Requirements
   • Exceptions
9. Calibration
   • Purpose
   • Key elements
   • Measurement frequency
   • Timing
   • Standards
   • Procedure
   • Logs for due dates
   • Consultants and outside firms
10. Items to be calibrated
    • Production
    • Laboratory
    • Process instrumentation
    • Other items
11. Calibration actions
    • Out of calibration
    • Out of calibration investigation
    • Out of service
12. Documentation
    • Calibration master log
    • Stickers
    • Certificate of Calibration
    • Retention times

Quality Assurance

1. Introduction
   • Definitions
   • Regulations
   • Roles and direct reports
2. Suppliers and contractors
   • Purpose
   • Outsourcing
   • Outsourcing checklist
   • Activity: Audit Team
3. Materials and products
   • Purpose
   • Responsibilities
   • Approves or rejects
   • Incoming materials
   • Materials inspection
   • Material testing
   • Label specification
   • Control of labeling use
   • Non-conforming materials definitions
   • Non conforming materials
4. Investigations
   • Purpose
   • Investigations and reviews
   • Structure of a problem and investigation
   • Investigations must include
   • Returned product investigation
   • Complaint investigations
5. Documentation
   • Standard operating procedures
   • Process control records
   • Document review
   • Signature log
   • Audit
   • Deviation from standards
   • Annual product review
   • Annual product review required content
   • Annual product review content
   • Annual product review reminders
   • Scale up and post approval changes
   • Post approval change analytical testing laboratory site
6. Recall procedure
   Purpose
   Product-recall strategy
   Depth of recall
   Product-recall classification

Quality Control

1. Regulations
   • Subpart I - Laboratory controls
   • Establishes control mechanisms
2. Specifications and standards
   • What to check for
3. Sampling plans
   • Choosing a sampling plan
   • Steps to using a sampling plan
   • Types of sampling plans
4. Testing procedures
   • Requirements
   • Testing concepts
   • Testing and release for distribution
5. Roles and responsibilities
   • Review of analytical results
   • Analytical reviewer responsibility
6. Analytical results
   • When an OOS occurs
   • Average laboratory results
   • Test outcomes
   • Deviations
7. Investigations
   - Laboratory investigations
   - Written records include
8. Certificate of analysis
   - Purpose
   - Report content
9. Stability testing
   - Procedural requirements
   - Recent citations
   - Stability chamber
   - Determining expiration date
   - Accelerated stability
   - Reconstitution
   - Documentation
10. Reserve samples
    - Procedural requirements
    - Retention times
11. Other types of samples
    - Terminology
12. Documentation
    - Definitions
    - Proper documentation
    - Computer printouts
    - Correcting errors
    - Unacceptable habits

Validation
1. Introduction
   - Purpose
   - Validation life cycle
   - The business case for validation
   - Significant dates
   - Assessing validation need
   - Deciding what get validated
2. Qualification
   - Qualification versus validation
   - Flow chart
   - Design qualification
   - Installation qualification
   - Operation qualification
   - Performance qualification
3. Qualification documentation
   - Design qualification protocol
   - Installation qualification protocol
   - Operation qualification protocol
   - Performance qualification protocol
   - Protocol supplement
   - Protocol deviations
4. Validation
   - Definitions
   - Process validation
   - State of control
   - Batch control
   - Worst case
   - Edge of failure
   - Proven acceptable range
5. Validation timing
   - Prospective validation
   - Concurrent validation
   - Retrospective validation
   - Re-validation
   - Re-validation triggers

Cleaning validation
   - Purpose
   - Cleaning validation scope
   - Objectives
   - Acceptable levels of contamination
   - Impurity accept limit
   - Evaluation of cleaning validation
   - Case example
   - Activity: Validation
6. Validation documentation
   - Master plan
   - Validation protocol
   - Basic protocol
   - Final report
   - Report format
   - Protocol supplement
   - Summary and evaluation
   - Protocol certification
   - Documentation retention
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GMP Essentials Class

**GMP Essentials**

**Monday**

8:00 – 8:30 AM  Continental Breakfast
8:30 – 9:00 AM  Introduction
9:00 – 11:45 AM GMP Basics Part 1
11:30 – 1:00 PM  Lunch - Joe’s Crab Shack
1:00 – 4:30 PM  GMP Basics Part 2

**Tuesday**

8:00 – 8:30 AM  Continental Breakfast
8:30 – 11:30 AM GMP Intermediate Part 1
11:30 – 1:00 PM  Lunch - The Mandarin
1:00 – 4:30 PM  GMP Intermediate Part 2

**Wednesday**

8:00 – 8:30 AM  Continental Breakfast
8:30 – 11:30 AM GMP Advanced Part 1
11:30 – 1:00 PM  Lunch - Hard Rock Café
1:00 – 4:00 PM  GMP Advanced Part 2

4:00 – 5:00 PM  Presentation Assignments, Scheduling, and Preparation Time

**Notes:**

1. This class can be customized to meet your site requirements.