GMP Essentials for Drug Manufacturers

Purpose

Employees identify the essential elements of CGMP for beginning work in the pharmaceutical and biotech industries.

Objectives At the completion of the class, students will be able to:

1. State the historical development of CGMP regulations.
2. Explain the role and function of standard operating procedures.
3. Describe the personal role for contamination control.
4. Identify the sources of contamination.
5. List the common CGMP documentation practices.
6. Explain material controls.
7. State the common practices of production and process controls.
8. Explain the importance of an adequate, appropriate, and sufficient building design.
9. State the requirements of equipment design and construction.
10. List the requirements for building, and equipment cleaning and maintenance.
11. Explain the role of quality assurance.
12. Explain the role of quality control.

Prerequisite

None

About the Class

1. This class uses group-facilitated discussion, multi-media, problem solving activities and facilitated instruction to develop a solid understanding of CGMPs.
2. The optional final exam is approximately 25 questions.
3. Each student receives a student guide containing a representation of the program's slides and graphics with space provided for note taking.
4. This class can accommodate up to 25 people.
5. Duration: 16 hours.

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On-Site Series

Topics Covered

Past, Present, and Future
1. Definitions
2. Perspectives 1900-1962
3. Activity: *Heard On The Street*
4. From 1962 to the present
5. New issues and practices
6. Quality by Design
7. Design of Experiments
8. Design Space
9. Risk Assessment
10. 21CFR211 – Multi-media presentation
11. Consequences of non-compliance

People & Responsibilities
1. Personnel
2. Management
3. Organization and personnel
4. Training
5. Consultants and contractors

Standard Operating Procedures
1. QA responsibility
2. Uses of procedures
3. Writing, formatting and guidelines
4. Revisions and approval
5. Review frequency
6. Activity: *Writing Procedures*

Contamination
1. Contamination Control – Multi-media presentation on GMPs
2. Sources of contamination
3. Personal methods of contamination control
4. Penicillin controls

Personal hygiene
1. Rest rooms and hand washing
2. Clothing to be worn
3. Clean room activities

Documentation
1. Completion, checking, and correcting documentation
2. Error descriptions
3. Non-compliant practices
4. Fraud and falsification policy
5. Case Study: *Able Pharmaceuticals*
6. Activity: *Real-time Documentation*

Materials
1. Supplier qualification
2. Material specifications, controls and identification
3. Sampling
4. Activity: *Bead Sort*
5. Receiving materials
6. Non-conforming materials
7. Activity: *Design a Product*

Packaging and Labeling
1. Labels and labeling
2. Content of Labels
3. Material examination
4. Material controls
5. Branding
6. Label issuance
7. Packaging and labeling operations
8. Expiration dating
9. Specifications
10. Tamper-evident packaging
11. Case study: *McNeil's Tylenol*
12. Activity: Design A Label

Production and Process Controls
1. Common Controls
2. Weighing of materials
3. Charge-in of active ingredients
4. Amount of active ingredient
5. Calculation of yield and values
6. Equipment identification
7. Statistical, random, or representative sampling
8. Finished product and in process testing
9. Time limitations on production
10. On line testing
11. Microbiological contamination control
12. Reprocessing
13. Documentation
14. Activity: *Inspection Detection Subpart F*

Buildings and Facilities
1. Design and construction features
2. Special construction considerations
3. Sufficient space defined
4. Product, equipment, material flow
5. Designated and defined spaces with examples
6. Rationale for environmental monitoring
7. Methods and parameters
8. Demonstrated control
9. Penicillin contamination
10. Lighting
11. Air systems
12. Water
13. Facility alarms
14. Waste
15. Housekeeping
16. Activity: *Design A Facility*

Equipment Design and Construction
1. Appropriate and suitable
2. Equipment selection
3. Blue prints of process
4. Control devices
5. Equipment construction materials
6. Lubricants
7. Filters design and specifications
8. HEPA Filters
9. Equipment use, cleaning and maintenance
10. Procedures and training
11. Levels of cleaning
12. Equipment cleaning logs
13. Work orders and repair orders
14. Log requirements and exceptions
15. Activity: *Design A Dream Car*

Calibration
1. Key elements
2. Measurement frequency
3. Timing, standards, and procedure
4. Logs for due dates
5. Consultants and outside firms
6. Out of calibration responsibilities
7. Out of service
8. Calibration documentation

Laboratory Purpose and Regulations
1. Subpart I - Laboratory controls
2. Establishes control mechanisms
3. Specifications, Sampling, and Testing
4. Choosing and using a sampling plan
5. Testing and release for distribution
6. Certificate of analysis
7. Analytical Results
8. When an OOS Occurs
9. Average laboratory results
10. Laboratory investigations
11. Stability Testing
12. Procedural requirements
13. Recent citations
14. Stability chamber
15. Determining expiration date
16. Accelerated stability
17. Reconstitution
18. Reserve Samples
19. Procedural requirements
20. Retention times

The Role of QA
1. Definitions and regulations
2. Roles and direct reports
3. Suppliers and Contractors Qualification requirements
4. Outsourcing and checklist
5. Approvals or rejections
6. Incoming materials
7. Materials inspection and testing
8. Labeling specifications
9. Labeling control and use
10. Non-conforming materials
11. Investigations
12. Investigations and reviews
13. Structure of an investigation
14. Investigation content
15. Types of investigations
16. QA Documentation
17. Product recall strategy
18. Depth of recall
19. Product recall classification
20. Activity: *Design An Audit*

Summary
1. Activity: *GMP Challenge*

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