MASTER GMP BOOT CAMP - 101

3-DAY PHARMACEUTICAL CGMP BOOT CAMP

COMPLIANCE FROM THE AUDITOR'S PERSPECTIVE

6TH, 7TH & 8TH OF NOVEMBER 2019

SPRINGHILL SUITES NEW ORLEANS DOWNTOWN/CONVENTION CENTER
301 ST. JOSEPH STREET NEW ORLEANS, LOUISIANA 70130 +1 504-522-3100

GMP Boot Camp (Block of Rooms)

All Boot Camps Conferences Includes:

- GMP Seminar Binders,
- Handbooks
- Certificates of Attendance
- Lunch and Coffee

GMP Boot Camp

Using real world applicability as learning tools from the Auditor's Observations and published warning letters.

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3-DAY CGMP BOOT CAMP TRAINING 'FROM THE AUDITOR'S PERSPECTIVE'

Training taught through use of Applicability observations.

Day 1 Agenda

08:00 Opening Introductions

08:30 GMP 101 The Basics - The required GMP Training for all employees who operate under Title 21 Compliance Requirements.

11:00 21 CFR Part 11 Basic Overview

- 21 CFR Part 11 Definitions, System Types and Classifications
- 21 CFR Part 11.10 Sections a) - k)
- Protection of Systems – Passwords and Security Measures

12:00 Lunch

12:30 21 CFR Parts 210/211 Drug GMPs - The Basics

- Organizational & Management Responsibilities
- Document Control Program
- Employee Orientation, Quality Awareness, and Job Training
- Plant Safety and Security
- Internal Quality/GMP Training Session Program
- Facility Design and Layout – BOD and Utilities
- Environmental Control Program
- Facility Maintenance and Good Housekeeping Program
- Outside Contractor Control Program
- Equipment Design, Placement and Identification
- Equipment Maintenance & Cleaning
- Material/Component Specification and Purchasing Control
- Material/Component Receipt, Inspection, Sampling, Testing, Storage and Handling
- Inventory Control Program Vendor (Supplier) Control Program
- Material/Component/Label Verification, Storage, and Handling

4:30 Questions and Answers (Q&A)

4:45 End of Day Wrap-up

John is the CEO of The Auditing Group, Inc. (www.auditing.com).

John also serves as the Senior Editor at GMP Publications, and CEO of The Validation Group.

More than 1200 GxP audits, Gap Analysis and remediation projects world-wide, with 30+ years, hands-on technical and management level experience within the Pharmaceutical, Biotechnology, Medical Device, Petrochemical, Validation, and regulated industries.

John has assisted hundreds of companies in meeting and exceeding regulatory compliance, pertaining to 'for-cause' or 'due-diligence' initiatives.

Helping companies to achieve, resolve, remediate and exceed regulated industry requirements, mandates, 'for-cause' and 'due-diligence' priorities with the technique of promoting GxP standards and practices through interactive hands-on training. Extensive knowledge in industry standards; FDA (CDER, CBER, CDRH, CVM, CFSAN), cGMP, GLP, ICH, GAMP, ISO, OECD, EPA and GCP regulations.

Day 2 Agenda

08:00 Opening Q&A and Recap

08:30 21 CFR Parts 210/211 Drug GMPs (Cont.)

- Equipment/Line/Area Cleaning, Preparation, and Clearance
- Operational Process Validation and Production Change Order Control
- In-Process Inspection, Sampling, and Laboratory Control
- Reprocessing/Disposition of Materials
- Finished Product Verification, Storage, and Handling
- Finished Product Inspection, Sampling, Testing, and Release for Distribution
- Complaint Handling and Customer Satisfaction Program
- Operational Process Validation and Production Change Order Control
- In-Process Inspection, Sampling, and Laboratory Control
- Reprocessing/Disposition of Materials
- Finished Product Verification, Storage, and Handling
- Finished Product Inspection, Sampling, Testing, and Release for Distribution

12:00 Lunch

12:30 21 CFR Part 820 Medical Device GMPs (With correlations to ISO 13485)

- 21 CFR Parts 820 and ISO 13483 Overview
- Quality System Requirements
- Management responsibility
- Quality audit
- Personnel
- Design Controls
- Document Controls
- Purchasing Controls
- Identification and Traceability
- Production and process controls
- Inspection, measuring, and test equipment
- Process validation
- Acceptance Activities
- Receiving, in-process, and finished device acceptance
- Acceptance status
- Nonconforming product
- Corrective and preventive action (CAPA)
- Device labeling and packaging
- Handling, Storage and Distribution
- Installation

4:30 Questions and Answers (Q&A)

4:45 End of Day Wrap-up

Day 3 Agenda

08:00 Opening Q&A and Recap

08:30 21 CFR Part 820 Medical Device GMPs (With correlations to ISO 13485) (Cont.)

- Records - General requirements
- Records - Device master record (DMR and what goes into the files)
- Records - Device history record (DHR and what goes into the files)
- Records - Quality system record
- Records - Complaint files
- Servicing
- Statistical Techniques (Different systems, software and qualifications)
- Recall and Traceability
- Corrective and Preventive Actions (CAPA)

12:00 Lunch (Flexible Timing)

Systems Validation Compiling the Validation Master Plan (VMP)

- Project Plan (PP) Development
- User Requirement Specifications (URS)
- Functional Requirement Specifications (FRS)
- Design Specifications / Design Qualifications (DQ)
- Installation Qualifications (IQ)
- Operational Qualifications (OQ)
- Performance Qualifications (PQ)

Combination Devices – The Basics Product Jurisdiction – 21 CFR Part 3

- Regulation of Combination Products – 21 CFR Part 4: Scope
- General Considerations for cGMP Compliance for Single Entity Products
- 211 and 820 applicability – A Risk Based Approach
- Streamline Approach
- Post Marketing Requirements
- Questions to the Agency

4:30 Questions and Answers (Q&A)

4:45 End of Day Wrap-up

GMP Boot Camp

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