MASTER GMP BOOT CAMP – 101

2-DAY MEDICAL DEVICE CGMP BOOT CAMP - MAY 14-15, 2020

21 CFR Parts, 11 Electronic Systems and 820 Medical Device GMPs, along with ISO 13485 Correlations

'FROM THE AUDITOR'S PERSPECTIVE'

LOS ANGELES AIRPORT MARRIOTT, 5855 WEST CENTURY BOULEVARD, LOS ANGELES, CA

Reference 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.

2-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.

- GMP - What is cGMP and the GMP Lifestyle?
- The Agency History and Objectives
- Roles and Responsibilities
- The 10 Principals of GMP
- Facility Management
- Agency Inspections and 483s
- The 5 Basic Binders
- The Quality Manual
- IT Strategy Plan
- Standard Operating Procedures
- Validation Documentation
- Drug/Device Documentation

11:00 21 CFR Part 11 Basic Overview

- 21 CFR Part 11 Definitions, System Types and Classifications
- 21 CFR Part 11 Electronic Records; Electronic Signatures – Predicate Rule
- Part 11.10 Sections a) - k)
    - Validation
    - Copies of records
    - Protection of records
    - Limiting system access
    - Audit trails
    - Operational system checks
    - Authority checks (h) Device checks
    - Education, Training, Experience
    - Policies and Procedures
    - Systems documentation
- Scope and Application Risk Analysis - Determine Which Systems Need to be Validated
- Steering Committee and Part 11 Initiatives

12:00 Lunch

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.

1:30 21 CFR Parts 820 QSR Medical Device GMPs - The Basics - (with ISO 13485 Correlations)

- Scope and Definitions
- Quality System Requirements
- Management responsibility
- Quality audit
- Personnel Requirements
- Design Controls
- Document Controls
- Purchasing Controls
- Identification and Traceability - Recall Process
- 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

4:30 Questions and Answers (Q&A)

4:45 End of Day Wrap-up

Day 2 Agenda

08:00 Opening Q&A and Recap

- 21 CFR Parts 820 QSR Medical Device GMPs (Cont.)

- Device labeling
- Device packaging
- Handling, Storage and Distribution
- Installation Requirements
- Records - General requirements
- Records - Device master record
- Records - Device history record
- Records - Quality system record
- Records - Complaint files
- Servicing
- Statistical Techniques
- Corrective and Preventive Actions (CAPAs)

12:00 Lunch

Validation and Qualification (Electronic Systems Overview)

4:30 Questions and Answers (Q&A)
4:45 End of Day Wrap-up

GMP Boot Camp

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