

## Aseptic Techniques

(1.5 hours)

Course Objectives:

- Review the GMP requirements for aseptic practices
- Reinforce the use of aseptic practices in the clean room during the manufacturing process

## Effective Writing

(4 hours/8 hours with workshop)

Course Objectives:

- Implement a standard writing style and format
- Sharpen your document reading and writing skills
- Effect a cultural change in how documents should be written and used
- Develop effective, user-friendly and GMP compliant documents
- Hands-on SOP writing

## Equipment Qualification

(1 day)

Course Objectives:

- Learn key terminology related to validation and qualification of equipment, processes and facilities
- Establish proper IQ, OQ, PQ documents
- Develop a standardized approach to report writing
- Establish key elements of change control

## Failure Investigations

(2.5 hours/4 hours with workshop)

Course Objectives:

- Improve your ability to write a failure investigation
- Minimize regulatory liability by learning how to appropriately document findings
- Enhance your understanding of what FDA expects to see from a failure investigation system
- Workshop: Hands-on investigation and documentation of a GMP manufacturing failure

## FDA QSIT Audit Approach

(2.5 hours)

Course Objectives:

- Review the FDA QSIT approach to inspection for pharmaceuticals
- Understand the FDA requirements expected for each quality subsystem
- Review the FDA rating system for failures in the quality system and the implications

## FDA Regulations (GMP, GCP and GLP)

(Length of time determined by the detail of the program and customization per client needs)

Course Objectives:

- Overview of quality and requirements for working in a regulated industry
- Overview of cGMP, GLP, GCP regulations and practical interpretation of the requirements
- Review of pertinent 483 observations related to either cGMPs, GLPs or GCPs

## GMPs in Research and Development

(2 hours)

Course Objectives:

- Understand what the GMP requirements are within research and development
- Review how the GMPs evolve through the development process
- Provide an overview of data integrity
- Learn how to provide a solid basis for development documentation that serves as the foundation for the development history report
- Review and discuss Warning Letters

## GMP/QSR Training

(Length of time determined by the detail of the program and can be customized to your needs)

Course Objectives:

- Overview of CGMP, QSR, or combination of both regulations
- Understand key definitions
- Review of pertinent 483 observations

## Great Documentation Practices

(2 hours/4 hours with documentation practice)

Course Objectives:

- Increase your awareness of FDA requirements
- Improve your documentation skills
- Reinforce that documentation is part of your job
- Enhance your understanding of compliance
- Hands-on documentation exercise

## Interacting with FDA

(1.5 hours)

Course Objectives:

- Discuss what the FDA looks for during an inspection
- Review key techniques for effectively interacting with the FDA
- Provide the "do's" and "don'ts" of interacting with the FDA

## Internal and External Auditing Techniques

(Length of time determined by the detail of the program)

Course Objectives:

- We train your audit team to prepare, conduct, and follow-up internal audits. We reference your SOPs and can provide supervised practice time for new auditors.

## ISO 13485:2003

(2 hours)

Course Objectives:

- Review ISO 13485 in detail and discuss the outputs based on the requirement

## Out-of-Specification (OOS) Issues

(1.5 hours/3 hours with workshop)

Course Objectives:

- Address the OOS guidance document
- Discuss how to handle OOS test results
- Review how the FDA views OOS
- Review 483 observations related to OOS
- Hands-on OOS exercise

## Overview of Methods Validation

(2.5 hours)

Course Objectives:

- Discuss method validation and verification concepts
- Review the development of methods from Phase 1 through Phase 3 Approval Inspection

## PAI Preparation and Planning

(3 hours/5-6 hours with workshop)

Course Objectives:

- Emphasize the importance of GMPs in development and transition to commercialization
- Identify techniques for assuring data integrity and accuracy
- Discuss the key preparatory activities (New Drug Application through Pre-Approval Inspection)
- Workshop of discussion of most feared questions

## Part 11 Compliance

(2 hours)

Course Objectives:

- Review Part 11 regulations
- Discuss key definitions
- Discuss Risk Management approach
- Review 483 observations related to Part 11 compliance

## QSIT Overview

(2.5 hours)

Course Objectives:

- Review objectives of QSIT Approach
- Describe QSIT subsystems
- Preparing for a QSIT inspection
- Discuss FDA warning letter observations

## Sampling Plans

(Length of time determined by the detail of the program, based on client's needs)

Course Objectives:

- Identify appropriate sampling plans for material in-process and finished product testing

## Technical Writing

(Length of time determined by the detail of the program)

Course Objectives:

- Apply knowledge to develop a technically accurate writing style
- Know the considerations to create a technically accurate report/document
- Evaluate and revise your writing before submitting your document
- Increase overall comprehension of the technical writing process
- Increase the overall effectiveness of writing style
- Develop clear and concise reports and documents

## Validation: Key Concepts and Planning

(1 day: can be expanded depending on depth of training needed)

Course Objectives:

- Learn key terminology related to validation and qualification of equipment, processes and facilities
- Learn format for master plan
- Ensure a consistent approach to preparing, executing, and documenting qualification and validation activities