GMP Auditing for Quality Assurance Training Course for FDA Regulated Industries

2 Day Virtual Seminar

Course Description

Auditing is a critical function within a pharmaceutical company. It provides management with information about how effectively the company controls the quality of their processes and products. Auditors must perform their jobs competently to ensure their company's compliance with pharmaceutical USFDA GMP regulations and other quality standards like ICH Q10. This Auditing for GMP course is specifically designed to address the challenges of GMP auditing for the pharmaceutical industry and present the basic competencies required to effectively perform the auditor's assigned responsibilities.

Learning Objectives

- Effectively evaluate audit and report findings
- Identify critical components for a good audit report
- Conduct an audit using an audit trail and checklist
- Understand the concepts behind compliance auditing
- Increased knowledge of cGMP concepts and regulatory requirements related to auditing
- Prepare and conduct audits using an audit trail and checklists
- Identify the critical competencies needed to be a conscientious auditor

2 Day Training Agenda

Background Information
Auditing Department Basics

- Exercise: Be, Know, Do

Traits/Skills of a Good Auditor

- Group discussion: Fishbone Diagram
- Group discussion: Exercise: Potential Interview Problems
- Group work: Exercise: Getting it Right

GMP Background Information for Auditors

- Exercise: Home Base Worksheet
- Exercise: Preamble Activity

Pre-Audit Information
Conducting the Audit

- Group work: Common Items to look for in an Audit

Post Audit

- Group work: Classifying, Managing, Justifying your findings
- Exercise: cGMP Compliance
- Exercise: Ranking – GMP Observations
- Group work: Root Cause Analysis 5 Why's
- Group work: Root Cause Analysis From Fishbone

Additional Resources and Worksheets/Checklists

- Calibration, Equipment and Validation Information
- Audit Strategies
- Additional Considerations for GMP Auditing
- Audit Report Example 1, Example 2, Example 3

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Who Should Attend

- This course is recommended for individuals with two to three years of direct experience working with the USFDA and PIC/S GMP guidelines who want to develop additional expertise in GMP Auditing
- New auditors or individuals wanting to become auditors
- Professionals who are responsible for conducting internal or vendor GMP audits
- Suppliers and others who are audited, such as quality assurance and quality control specialists, validation scientists, manufacturing supervisors, technical support personnel, engineers, and all levels of management

Faculty

Kelly Thomas

Ms. Thomas has over two decades of cGMP hands-on industry experience in both pharmaceutical and medical device manufacturing operations. Her experience covers all Quality Systems; as well as, all areas of validation; including, process/product validation, facilities validation, CSV and 21 CFR Part 11, test method validation, equipment/automated processes and cleaning validation.

REGISTRATION FORM

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Terms And Condition

- Registration shall be reconfirmed only once payment has been made prior to the course.
- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
- WCS reserves the right to make alterations to the conference/executive briefing content, timing, speakers without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of WCS. If such a situation arises, we will refund your registration fee or we will try to reschedule the event.