QUALITY CONTROL LABORATORY COMPLIANCE - CGMPS AND GLPS COURSE

2 DAY VIRTUAL INSTRUCTOR LED COURSE

What Regulatory, Compliance & Quality Professionals Need to Know

COURSE DESCRIPTION

The pharmaceutical quality control laboratory serves one of the most important functions in pharmaceutical production and control. A significant portion of the cGMP regulations pertain to the quality control laboratory and product testing.
As a minimum, each pharmaceutical quality control laboratory should receive a comprehensive GMP evaluation each two years as part of the statutory inspection obligation.

AREAS COVERED

- USP Interpretations
- Laboratory Walk-through Inspection Coverage
- General GMP Requirements and Laboratory Controls
- Samples, reagents and reference standards
- Instrument calibration, maintenance, qualification and logbooks
- Investigations and change control
- Personnel qualification and training
- Stability program
- Raw material reduced testing program
- Retention sample program
- Microbiology Laboratory Controls
- Media control and media growth promotion, sterility testing, methods validation
- Laboratory Procedures and Documentation
- SOPs, raw data, electronic records
- Analytical Method Validation
- Laboratory OOS: Investigations and Retesting
- Elements of a Robust Data Integrity Program

LEARNING OBJECTIVES

- Discuss cGMPs as defined in 21 CFR 211 for Quality Control units, and how they apply to QC regulatory requirements
- Discuss GCP Laboratory regulatory requirements.
- Know how to efficiently address deviations and OOS results
- Discuss equipment calibration, qualification, and methods validation
- Explain the importance of accurately maintaining appropriate documentation

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AGENDA

DAY 01

- Session Start
- Seminar objectives review, expectations and scope.
- Review Regulations governing QC lab
- QC lab layout
- Equipment Overview
- Qualification
- Calibration
- Maintenance
- Documentation requirements
- Personnel qualification and training
- Stability program
- Raw material reduced testing program
- Retention sample program

DAY 02

- Analytical Method Validation and Transfer
- Data Integrity Program
- OOS Investigations
- Customer Compliant Investigations / Adverse Events

FACULTY KELLY THOMAS

Kelly Thomas, Vice President at America's Quality Operations, has 20 years of hands-on experience in the industry. She has worked with reputed facilities like FDA, EMEA, IMB, JP, and Health Canada.Her core expertise includes computer system validation, equipment process validation, and facilities validation. In addition, she will guide you on implementing a robust quality system, evaluating the KPIs of the facility, and executing high-quality management.

REGISTRATION FORM

Name _____ **Email** _____

Organization _____ **Department** _____ **Position** _____

Phone _____ **Mobile** _____

Register Online At www.worldcomplianceseminars.com

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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.