QUALITY CONTROL LABORATORY COMPLIANCE – CGMPS AND GLPS TRAINING

COURSE DESCRIPTION

FDA inspection and oversight of quality control (QC) laboratories are essential elements of the agency's evaluation of the compliance status of regulated companies representing multiple industries - pharmaceuticals, biologics, medical devices, as well as foods and cosmetics - as well as the contract QC laboratories which service these industries. Lack of compliance can result in severe regulatory actions, criminal liability, fines, and the inability to obtain product approvals.

This course will examine the fundamental requirements for all QC laboratories subject to FDA inspection, recent trends from FDA inspection reports and enforcement actions. In addition, this course will include a list of relevant regulations and guidelines and demonstrate how quality control and quality assurance personnel can monitor industry practices to stay "current" with FDA requirements (cGMPs and GLPs).

Learning Objectives

Key goals of the conference will include learning:

- The basics of FDA law and regulations governing QC laboratories responsible for testing research materials, components of FDA-regulated products, and finished FDA-regulated products (pharmaceuticals, biologics, medical devices, cosmetics, and foods).
- Laboratory organization, personnel qualification and training requirements.
- Documentation and record-keeping requirements, including e-records and data integrity.
- Sample integrity requirements.
- Management and control of stability (shelf-life) studies.
- Analytical methods verification and validation.
- Management and control of laboratory instruments.
- Management and control of laboratory supplies.
- Proper conduct of laboratory investigations.
- Consequences of laboratory non-compliance.

Who Will Benefit

Senior directors, managers, supervisors and those who have responsibility for ensuring that QC laboratory operations and practices comply with current good manufacturing practices and good laboratory practices.

- Quality Assurance
- Quality Control
- Research & Development
- compliance.

Our faculty

Kelly Thomas

Our trainer 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

Utilizing strategic thinking, risk based approaches, and Lean principles, she has demonstrated success in steering and managing complex projects within the pharmaceutical and medical device industries.

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Agenda

DAY 01

Session Start

Basics of FDA law and regulations for QC laboratories

What is adulteration?

- Pharmaceuticals
- Biologics
- Medical Devices
- Foods
- Cosmetics
- What is CGMP?
- Pharmaceuticals
- Biologics
- Medical Devices
- Foods
- Cosmetics
- What is GLP?
- What is AIP?
- Contract Laboratories
- FDA inspection methodology

Laboratory Organization

- Organization
- Personnel qualification and training

Documentation and record-keeping requirements

- Standard Operating Procedures
- Analytical Methods
- Raw data (notebooks, print-outs)
- Document management (change control, retention)
- Part 11 (electronic records and signatures)

Sample integrity requirements

- Sample collection
- Sample delivery, handling, disposition
- Retain samples

Stability (shelf-life) studies

- Organization and management
- Storage units
- Analytical methodology

DAY 02

Analytical methods verification and validation

- Protocols
- Tests
- Documentation

Management and control of laboratory instruments

- Qualification
- Calibration
- Maintenance

Management and control of laboratory supplies

- Standards
- Reagents, chemicals

Proper conduct of laboratory investigations

- Out-of-specification results
- Out-of-norm results
- Root cause analysis
- Documentation

Consequences of laboratory non-compliance