COBBLESTONE

COURSE ID 2926

Laboratory Controls Overview & Establishment of Specifications

GMP Laboratory Control Professional Certification Program

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- FDA Systems Based Inspections
- Specification Examples
- ICH Q3B
- ICH Q6A

about the course

In FDA's Guide to Inspections of Pharmaceutical Quality Control Laboratories (7/93), it is stated "The pharmaceutical quality control laboratory serves one of the most important functions in pharmaceutical production and control. A significant portion of the CGMP regulations (21 CFR 211) pertain to the quality control laboratory and product testing." Consistent with current Good Manufacturing Practices (cGMPs), such testing must always be performed using a product specification based on sound scientific principles and approved by the Quality Control unit.

This 90-minute accredited training course will provide participants with a broad understanding of the requirements for establishing a drug product specification that meets these FDA expectations. Current accepted practices of following ICH guidelines for establishing universal and specific tests as well as specifications for organic impurities will be covered.

This training is one part of the 10-course series required for the GMP Laboratory Control Professional Certification Program.

Attend this as a step in the certification process or as a stand-alone course for personal career advancement and training.

who should attend

This course is intended for professionals in the Pharmaceutical or Biological industries who are responsible for either the establishment or approval of drug product specifications within a regulated environment.
This course will benefit individuals in:

• R&D	• Quality Control
• Quality Assurance	• Technical Operations
• Manufacturing	

In addition, individuals within Regulatory Affairs who often review these documents will benefit from this training.

learning objectives

Upon completion of this course, you will be able to:

- List and explain the six systems that FDA includes in their systems-based inspections
- Explain the specific areas that FDA will focus on in a laboratory inspection
- Create a drug product specification that meets ICH and FDA requirements
- Select appropriate organic impurities specifications consistent with ICH requirements

course outline

Review of Learning Objectives
Module 1: Overview of Laboratory Operations

- FDA Systems Based Inspections
- cGMPs Related to Laboratory System
- FDA Laboratory Inspection Guideline

Module 2: Establishing Scientifically Sound Specifications

- ICH Q6A
- Three Types of Products
- Challenges

Module 3: Establishing Organic Impurities Specifications

- ICH Q3B
- Three Types of Impurities
- Three Types of Levels
- Specification Examples

Assessment Opportunity

course instructor

David E. Wiggins is an Analytical/Stability Consultant within the pharmaceutical industry with a focus on pre-market stability, analytical method validation and method transfer.

Mr. Wiggins was previously Sr. Associate Director of Analytical Development for Bayer Consumer Care. Prior to joining Bayer, Mr. Wiggins worked for Schering-Plough and Merck with responsibility for Method Optimization, Method Validation, Method Transfer and Stability (both pre- and post-market). These responsibilities have additionally included involvement with multiple NDA submissions, ANDA submissions and FDA general and PAI inspections.

Mr. Wiggins has over 35 years of experience in the pharmaceutical industry in both a QC and an R&D setting. During this time, he has been instrumental in establishing and updating stability and method validation policy to be consistent with the changing regulatory requirements. Mr. Wiggins has frequently lectured on stability and analytical method validation in the US, Puerto Rico, and throughout Europe. He has been active in submitting comments and validated stability-indicating analytical methods to the U.S. Pharmacopeia and has been an invited speaker to FDA, university, and industry conferences.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)
Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.