COBBLESTONE

COURSE ID 2927

Analytical Methods Validation - 21CFR211.165(e)

GMP Laboratory Control Professional Certification Program

DIRECTED BY

David E. Wiggins — Analytical/Stability Consultant

90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- FDA CDER Requirements
- ICH Validation Requirements
- Evaluating Method Robustness
- Current Guidelines

about the course

One of the most critical factors in developing and marketing pharmaceutical drug substances and drug products today is ensuring that the analytical methods used for analysis can generate valid data upon which business and regulatory decisions can be made. FDA, ICH and USP have each recognized the importance of this to the drug development process and have separately expanded method validation requirements in recent years. However, with only limited guidance, industry has been left to interpret how to adequately comply with the regulations.

Whether involved in method development, method validation, method optimization or method transfer, this 90-minute, accredited training course will provide a broad understanding of the method validation process and the difficulties encountered in validating methods to comply with today's upgraded FDA CDER requirements.

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 individuals who have the responsibility for establishing the integrity of analytical methods for active pharmaceutical ingredients (APIs) or finished pharmaceutical dosage forms.

This course will benefit individuals in:

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

learning objectives

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

- Summarize Key Validation Factors
- Identify the Current Method Validation Guidelines
- Identify the Current FDA Method Validation Requirements
- Recommend an Appropriate Technique for Evaluating Method Robustness

course outline

Review of Learning Objectives

Module 1: Definitions, Purpose, Regulations & Guidelines

- Definitions, Purpose, Key Factors
- Regulations
- Guidelines

Module 2: ICH Validation Requirements for Assay Method

- Specificity
- Linearity (Range)
- Accuracy
- Precision

Module 3: FDA Requirements Beyond ICH & Impurity Assay

- Robustness
- DL / QL

Question and Answer Session

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.