COBBLESTONE

COURSE ID 1887

Analytical Methods Validation for FDA Compliance

DIRECTED BY

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18 HOUR

ACCREDITED COURSE

Course Topics Include:

- FDA, ICH and USP Validation Requirements
- Applying Validation Studies Consistent with Method Purpose
- GMP Compliance during Validation
- Validation Acceptance Criteria
- Validation Statistics
- Validation Protocol Workshop
- Validation Reports
- Revalidation
- Method Transfer

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 verification or method transfer, this course will provide a broad understanding and "hands-on" knowledge of the method validation process and the difficulties encountered in validating methods to comply with today's upgraded FDA CDER requirements. Lectures will include not only theoretical basis and practical applications, but actual validation examples of HPLC, GC, UV/Vis, AA and titration methods for small organic molecules. Some of the more common mathematical and statistical treatments of validation data will also be discussed. Because of the tremendous effort that can be expended in conducting validation studies, efficiency of experimental design and documentation will be stressed throughout the discussions.

Although the general principles in this course may be applied to methods for testing biological molecules and medical devices, the focus of this course is on the validation of methods for the analysis of small molecules and not the unique analytical procedures often used for testing products of a biological nature.

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

Regulatory affairs personnel as well as regulatory authorities who are responsible for the review of such data will also benefit from this course.

learning objectives

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

- Identify the current method validation requirements from FDA, ICH and USP guidance documents and from industry practices
- Design focused and efficient method validation protocols that meet all FDA CDER regulatory requirements
- Demonstrate the knowledge to confidently establish validation acceptance criteria
- Explain the GMP expectations for validation
- Describe the key issues in documenting validation work and writing reports
- Explain the requirements and common issues in method transfer and revalidation

course outline

Review of Learning Objectives/Methods Validation Background

- Definitions, Purpose and Benefits
- Key Validation Factors
- Development, Validation, Verification, and Transfer
- Regulatory Requirements and FDA Inspections
- ICH/USP/FDA Validation Guidelines

- **ICH/USP/FDA Validation Requirements**
- Specificity
- Linearity
- Range
- Accuracy
- Precision
- Robustness
- DL/QL

Historical Validation Parameters

- Selectivity
- Bias
- Sensitivity
- Reproducibility
- Ruggedness

Methods Validation cGMP Practices

- FDA Warning Letters and 483 Citations
- Validation SOPs and Protocols
- Validation Samples and Standards
- Instrument Qualification
- Training

Methods Validation Applications

- Test Selection
- Product Specification
- Development vs. Validation
- Method Write Up
- Experimental Design

Methods Validation Statistics and Acceptance Criteria

- Application of Statistics to Validation Data
- Statistical Power
- Commonly Used Acceptance Criteria
- Critical Concepts Regarding Validation Data and Criteria
- Recommended Approach for Setting Criteria

Methods Validation Workshop

- Participants will develop and discuss method validation experimental plans and acceptance criteria

IND Phase Methods Validation

- IND timeline
- FDA Guidance on IND Phase Validations
- Examples of Development/Validation Studies
- Questions and Answers Relating to Participants' Own
- Validation Problems

Method Transfer

- Four Options from USP<1224>
- Method and Lab Readiness
- Training, Testing and Data Evaluation

Method Validation Data and Reports

- Experimental Documentation
- Elements of a Good Report
- IND/NDA Reports

Revalidation and Methods Update

- Drug Substance Changes
- Drug Product Changes
- Method/Site Changes
- Technology Changes
- FDA Mandated Update

Assessment Opportunity

course instructor

Dr. J. Mark Green is an Analytical Chemistry Consultant, providing expertise and practical guidance in analytical development from pre-IND phase through commercialization.

Dr. Green was previously Director of Pharmacy and Analytical Development with Lautheus Medical Imaging, where he was responsible for the development, validation, and transfer of analytical methods for drug substances and drug products. Additionally, he was responsible for stability testing, analytical support of safety assessment studies, and the preparation of CMC sections of regulatory submissions.

Dr. Green has over 30 years of experience in drug development, and previously worked for Bristol-Myers Squibb, DuPont Merck and DuPont. He has published and lectured on analytical method validation, and on applications of HPLC, TLC, and Chiral Chromatography. Dr. Green received his PhD in Analytical Chemistry from the University of Illinois.

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' 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)
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