

PAYMENT

\$2150.00 PER PERSON (INCLUDES BREAKFAST & LUNCH)

EARLY BIRD DISCOUNT

If you register at least thirty days in advance you will receive a \$200 discount on the course.

ADDITIONAL DISCOUNTS

Contact us at 610-648-7550 or info@cfpie.com for information regarding partnership discounts or how your organization can become a partner with CfPIE.

CANCELLATION POLICY

All cancellations must be in writing and are subject to a \$350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher good for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the \$350.00 cancellation fee.

If a registered attendee does not cancel and fails to attend, neither a refund nor voucher will be issued. All course cancellations must be in writing and emailed sent to info@cfpie.com. Registrants are responsible for contacting the hotel and canceling their room reservations.

CfPIE reserves the right to alter the venue, if necessary.

Substitution Policy - Classroom Courses

Substitutions are accepted at no penalty with written notification from the original registrant in advance of course. All substitution requests must be in writing and emailed to info@cfpie.com.

CfPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.

ABOUT CfPIE

Learn from the Leader

In a life sciences industry that has faced nearly \$15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

HOW TO REGISTER

1.

Go to <http://www.cfpie.com>

2.

Go to “REGISTER HERE” and select your course.

3.

Create an account and register for your course.

The Center for Professional Innovation & Education, Inc.
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<http://www.CfPIE.com>



ANALYTICAL METHOD VALIDATION FOR BIOLOGICS, BIOPHARMACEUTICALS AND OTHER THERAPEUTIC PRODUCTS

2019

March 6 & 7 - Los Angeles, CA

July 17 & 18 - Boston, MA

November 6 & 7 - Malvern, PA

COURSE DESCRIPTION

Complex processes yielding complex products such as biologics and biopharmaceuticals demand numerous, non-compensated, and sometimes complex QC test methods to confirm manufacturing consistency and product quality. This course provides a comprehensive overview of the international regulatory authority requirements and expectations for test method validation of these assays. This course will prepare attendees with the knowledge and tools to plan and execute test method validation packages for the NDA, BLA and MAA market application dossiers, covering in-process, release and stability assays commonly used by QC in biologic and biopharmaceutical companies. The course will cover validation of QC analytical test methods (e.g., electrophoretic, HPLC, peptide mapping, etc.), cell-based potency bioassays, immunochemical binding impurity assays and adventitious agent assays.

WHO SHOULD ATTEND

This two-day course is designed for those who perform, supervise, manage, audit, or oversee the validation of test methods for the quality control of biologic and biopharmaceutical products. This includes, but is not limited to, professionals in Analytical Development, Quality Control, Quality Assurance, and Validation groups. The course will also benefit those in other departments who find test method validation among their responsibilities.

INSTRUCTOR CREDENTIALS

John Geigert, Ph.D., RAC, is President of BioPharmaceutical Quality Solutions, which for the last 12 years has specialized in providing CMC regulatory strategy consulting for the biopharmaceutical and biologic industry.

Dr. Geigert has over 35 years of CMC industrial experience and leadership in the biopharmaceutical industry. He has held senior management positions as Vice President of Quality at both IDEC Pharmaceuticals Corporation in San Diego and Immunex Corporation in Seattle, and he was Director of Product Development for Cetus Corporation in Emeryville, CA. At these companies, he led the CMC efforts to obtain regulatory approvals for 6 biopharmaceutical products (4 recombinant proteins and 2 monoclonal antibodies) now commercially available in the U.S. and Europe.

He has served on the PDA Board of Directors, co-chaired the PDA Biotech Advisory Board, and served as an expert member of the USP Biotechnology Committee.

He obtained his B.S. in Chemistry from Washington State University, and his Ph.D. degree in Organic/Analytical Chemistry from Colorado State University.

LEARNING OBJECTIVES

Upon completion of this course, attendees will have a clear understanding of international regulatory authority regulations, and expectations and will have gained the background knowledge necessary to effectively plan and execute QC test method validation programs. Participants will have gained expertise in writing test method validation protocols and reports and in setting acceptance limits for validation. Additionally, attendees will have acquired insight into how to avoid common validation pitfalls and be able to quickly discriminate compliant from non-compliant test method validation activities.

HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CfPIE room rate of \$152/night if booked 3 weeks in advance of the course date)

The Desmond Hotel & Conference Center, Malvern, PA (CfPIE room rate of \$136/night if booked 3 weeks in advance)

Club Quarters Hotels, Boston, MA (CfPIE room rate of \$230/night if booked 4 weeks in advance).

The Berlin Hilton, Berlin, Germany (CfPIE room rate of Standard Single Room is €179.00 and Double Occupancy is €199.00 inclusive of VAT and Breakfast if booked 4 weeks in advance.)

FIRST DAY

Regulatory Requirements/Guidance on Analytical Method Validation

- Terminology defined: scientifically sound and appropriate, qualification, validation, revalidation and verification
- FDA, EMA, ICH and WHO requirements and guidance
- Validation lifecycle for analytical methods
- When during clinical development is analytical method validation required?

Analytical Method Validation Building Blocks

- ICH Q8, Q9 and Q10 adherence
- Validation Master Plan link
- QC instrumentation qualification
- Critical assay reagent qualification

Analytical Method Validation Characteristics

- Specificity, accuracy, linearity, precision
- LOD and LOQ
- Robustness and stability-indicating
- Value of system suitability controls

Validation Exercise: Quantitative Impurity ELISA (Host Cell Proteins)

- Detecting trace amounts of contaminating protein in a protein product
- Acceptability of generic critical reagents
- Preparation and characterization of process-specific critical reagents
- LOQ determination for multi-component ELISAs

Test Method Validation Protocol

- 8 basic elements of a validation protocol
- Pre-planning and planning steps
- Identification and documentation of assay characteristics needing to be validated
- Critical importance of assigning pre-defined acceptance criteria

SECOND DAY

Validation Exercise: Quantitative Potency Bioassay (Cell Lysis)

- Adequate bioassay development and optimization precedes validation
- Impact of physics, biology, chemistry and mathematics on bioassay performance
- Dilutional linearity
- Regression line analysis

Test Method Validation Report

- **11 basic elements of the validation report**
- **Relationship of the validation protocol to the validation report**
- **Meeting the pre-defined acceptance criteria**
- **Handling deviations, when (not if) they happen**

Test Method Validation Protocol

- 8 basic elements of the validation protocol
- Pre-planning and planning steps
- Identification and documentation of assay characteristics needing to be validated
- Critical importance of the pre-defined acceptance criteria

Validation Exercise: Enzymatic/HPLC Protein Identity Assay (Peptide Mapping)

- Achieving consistent peptides chromatographic fingerprints
- Comparison to the fingerprint of a well-characterized reference material
- Appropriate system suitability controls for the chemical modification, enzymatic digestion and chromatographic performance
- Specific assay characteristics to validate

Regulatory Authority Concerns About Test Method Validations

- Report card from the regulatory authorities on test method validation
- Validation issues identified during the review of the submitted market dossier
- Validation issues identified during regulatory inspections
- Test method validation “continuous improvement” – ICH Q10

Validation Exercise: Nucleic Acid Amplification (Mycoplasma PCR)

- Inclusion specificity for rapid detection of adventitious agents
- LOD determination of mycoplasma contamination in bioreactors
- Universal DNA primer selection
- System suitability control selection