**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.

**DEVELOPMENT AND VALIDATION OF BIOANALYTICAL ASSAYS FOR BIOLOGICS**

**INSTRUCTOR:** ROBERT DODGE, PH.D.

December 10 - 11, 2018 - Los Angeles, CA

April 24 & 25, 2019 - Los Angeles, CA

**COURSE DESCRIPTION**

Part 1: Quantitation Assays

Quantitation assays are critical for the development of biologics and biopharmaceuticals as well as accurate detection of protein biomarkers. Immunoassays for quantitation of protein drugs in biological matrices (ex. plasma, serum, tissue) generally take much longer to develop and are subject to a wider range of interferences than traditional xenobiotic small molecule quantitation assays by LC-MS/MS. Part 1 of this interactive two day course focuses on these critical assays and will take you step-by-step through the development of quantitation assays for proteins including monoclonal antibodies.

Part 2: Immunogenicity Assays

Part 2 of this course starts with an overview of immunology followed by the requirements of an immunogenicity program, including the establishment of a tiered testing approach for screening, confirmation assay analysis, titer assays and neutralizing antibody assays. The course then goes on to cover basic development of these assays, highlighting how to develop and label critical antibody reagents, different assay formats (ex. bridge, sandwich), including an analysis of strengths and weaknesses of each format.

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INSTRUCTOR CREDENTIALS

Dr. Robert Dodge has worked in the Pharmaceutical Industry for 20 years in both CMC manufacturing of Biologics and Bioanalytical testing of Protein Drugs and Biomarkers. Dr. Dodge was Director of Immunochemistry and Cell Biology at the Pharmanet Development Group, a contract research laboratory specializing in bioanalytical assay development and sample testing. His group developed assays for drug quantitation, immunogenicity testing and biomarker detection. Before this, he was co-founder and Laboratory Director at Princeton Bio Lab. This GLP/GMP-compliant contract research laboratory specialized in cell-based assays for protein therapeutics and was sold to Pharmanet in 2007.

Previously, Dr. Dodge spent 10 years at Bristol-Myers Squibb. Starting in the Immunology Department of the Pharmaceutical Research Institute, he later moved into biologic drug development and characterization. While there, he developed bioassays, neutralizing antibody assays and ligand binding assays. He also characterized biologic drugs, developed biomarker assays, interacted with the FDA regarding regulatory filings and managed a staff of scientists. He is currently a Director in the Bioanalytical Sciences Group at Bristol-Myers Squibb.

Dr. Dodge received his Ph.D. from Cornell University, where he also completed an NIH post-doctoral fellowship.

LEARNING OBJECTIVES

Upon completion of this course, attendees will have a clear understanding of regulatory agency expectations for bioanalytical development, and will have gained the background knowledge necessary to effectively plan bioanalytical assay development and validation programs for both quantitation assays and PK studies. Additionally, participants will learn to develop immunogenicity assays for detecting anti-drug antibodies for both marketed products and products in clinical development. Attendees will develop expertise in writing protocols, reports performing calculations, and acceptance limits for bioassay method validation.

FIRST DAY

Session 1: Immunochemistry Basics
Types of assays overview
Antibody chemistry, class, and sub-type
Preparation and purification of monoclonal and polyclonal antibodies

Session 2: Assay Formats
Basic sandwich ELISA format
Alternative formats (ex. direct, competition)
Detection techniques (ex. absorbance, luminescence)
Multiplexing
Instrument platforms
Critical reagent qualification

Session 3: Modeling and Analyzing Data
Equilibrium equations
Linear, four and five parameter curves
Anchor Points
Troubleshooting assay performance using curve model results
Determining precision, accuracy and total error following white paper guidance
Normal distributions relevant to assay acceptance criteria

Session 4: Assay Validation
Test method SOPs
FDA and draft EMA guidance for assay validation
Current required parameters for assay validation
Fit for purpose biomarker validations
The validation report
Incurred sample reanalysis

Session 5: Practical Development and Validation Workshop
Review and troubleshooting of simulated development data
Calculating accuracy and precision of an assay with simulated data

SECOND DAY

Session 6: Immunology
Basic immunology
Vaccines and protein drugs
Immunogenicity predication
IgE versus IgM/IgG immune response

Session 7: Testing Considerations
Pre-clinical versus clinical testing
Platforms
Case study of IgE response

Session 8: Bioanalytical Testing
Screening assay formats
Confirmatory assay
Titer assay
Neutralizing antibody assay
Overview
Examples
Functional versus effector function assays for antibody drugs

Session 9: Assay Design
Practical considerations
Positive controls
Statistical treatment and assay validation
Common interferences
Detection platforms

Session 10: Regulatory Guidelines for Validation
EMA guidance
FDA draft guidance
EMA draft guidance for monoclonal antibodies

Session 11: Risk Based Approach to Testing
Likelihood and consequences considerations
Historical antidrug antibody responses
Scientific white papers

Session 12: Assay Validation and Cut-Point Determination Workshop
Scientific white papers
Calculation software and methodology
Example calculations

HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CPIE room rate of $152/night if booked 3 weeks in advance of the course date)
The Desmond Hotel & Conference Center, Malvern, PA (CPIE room rate of $136/night if booked 3 weeks in advance)
Club Quarters Hotels, Boston, MA (CPIE room rate of $230/night if booked 4 weeks in advance).
The Berlin Hilton, Berlin, Germany (CPIE 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.)