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.

Go to http://www.cfpie.com
Go to “REGISTER HERE” and select your course.
Create an account and register for your course.

COURSE FEE
$2150.00 PER PERSON

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.

DEVELOPMENT AND VALIDATION OF BIOANALYTICAL ASSAYS FOR BIOLOGICS

INSTRUCTOR: Dominique Gouty, Ph.D.

ALL 2020 COURSE DATES WILL BE OFFERED VIRTUALLY THROUGH LIVE INTERACTIVE SEMINARS

Oct 19 & 20, 2020 (BST)
Dec 3 & 4, 2020 (PST)

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.
INSTRUCTOR CREDENTIALS

Dr. Dominique Gouty has worked in the Pharmaceutical Industry for 30 years in both CMC manufacturing of Biologics and Bioanalytical testing of Protein Drugs, Cell Therapies and Gene Therapies as well as Biomarkers.

PD: Dr. Gouty is USA Chief Scientific Officer at BioAgilytix, a contract research laboratory specializing in bioanalytical assay development and sample testing. Over her tenure, she has been involved in developing assays for drug quantitation, immunogenicity testing, neutralization and biomarker detection. She participated in the bioanalytical programs of 45% of the biologic drugs (including gene and cell therapies) approved by the FDA for the past 3 years. Before this, she was leading an international pharma division of a GLP/GMP-compliant contract research laboratory specialized in small and large molecule bioanalytical and analytical services. Dr. Gouty also has 15 years of prior industry experience as part of a career spanning R&D, clinical operation, and manufacturing in multiple multi-national pharmaceutical organizations such as Eli Lilly and J&J, as well as smaller biotech companies.

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
Critical criteria for a PK assay
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
Assay acceptance criteria and The importance of selectivity in assay development

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

Session 5: Biomarkers
Biomarkers are not PK assays : difference
Fit for purpose biomarker validation

Session 6: Practical Development and Validation Workshop
Review and troubleshooting of simulated development data
Calculating accuracy and precision of an assay with simulated data

Session 7: Immunology
Basic immunology
Immunogenicity for biologics, biosimilar, gene therapy and cell therapy. The different immune response

SECOND DAY

Session 8: Testing Considerations
Pre-clinical versus clinical testing
Different assay platforms: what to choose?
Case study of IgE response
Case study of a wrong platform selected

Session 9: Bioanalytical Testing
Screening assay formats
Confirmatory assay
Titer assay

Session 10: Assay Design
Practical considerations
Positive controls
Statistical analysis : Cutpoint (Calculation software and methodology)
Common interferences
Detection platforms

Session 11: Regulatory Guidelines for Validation
EMA guidance
FDA draft guidance
EMA draft guidance for monoclonal antibodies
Health agencies immunogenicity findings

Session 12: Risk Based Approach to Testing
Likelihood and consequences considerations
Historical antidrug antibody responses
Scientific white paper

Session 13: Neutralization Antibody Assay (NAb)
Overview & Examples
Functional versus effector function assays for antibody drugs
Validation critical parameters

Session 14: Practical Development and Validation Workshop
Review and troubleshooting of simulated development data
Calculating cutpoint of an assay with simulated data