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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” 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: Xiao-Yan Cai, Ph.D.

Please refer to our website for upcoming course dates and times

COURSE DESCRIPTION

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 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. This course then goes on to cover basic development of these assays, highlighting how to develop and label critical antibody reagents. This is followed by a review of current scientific guidelines on how to establish cut-points (with a hands-on calculation workshop with sample data at the end of the course). Optimization of screening assays to improve sensitivity and drug tolerance (amount of drug on board that can interfere with the assay) is also reviewed. Then we move into validation of the assays to support pre-clinical and clinical studies. The course will end with neutralization assays approaches.
INSTRUCTOR CREDENTIALS

Dr. Xiao-Yan Cai is co-founder and CEO of Accurant Biotech (熙宁/精翰生物检测), which is a CRO focusing on regulated large molecule bioanalytical services to support Pharma and Biotech clients for their innovative therapeutic biologics drug development.

Prior to co-founding the company about 3 years ago, Dr. Cai was global head for large molecule bioanalysis at WuXi AppTec’s Global Bioanalytical Services (BAS) from June, 2015 to December, 2017. Prior to that role, she was Director at Merck’s Bioanalytical Development division and had been with Merck and previously Schering-Plough (merged in 2009) for over 23 years.

She has extensive Biologics drug development experience and specializes in large molecule bioanalysis. Her team had developed/validated preclinical and clinical PK, PD, ADA and NAb methods to support all Schering-Plough and Merck’s biologics drug development pipeline, including Merck’s blockbuster immune-oncology drug anti-PD1 (Keytruda). She had been on the core BLA filing team for the successful FDA approval of Keytruda for late stage melanoma in 2014. She is also among the industry leaders for bioanalytical assay development and validation for Biosimilars. Her publications on this topic had been widely cited and considered as guiding white paper in the biosimilar bioanalysis field both globally and in China.

Dr. Cai holds a M.D. degree from Beijing Medical University in China (now part of Beijing University) and a Ph.D. in Biochemistry and Molecular Biology from University of Medicine and Dentistry of New Jersey (UMDNJ), which is now part of The Rutgers University in New Jersey, USA.

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.

Participants will have acquired insight into how to avoid common development and validation pitfalls and be able to quickly discriminate compliant from non-compliant validation activities. In addition, attendees will gain practical experience in applying what they have learned during hands on problem solving and calculations workshops.

FIRST DAY

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

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

Section 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
- The importance of selectivity in assay development

Section 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

Section 5: Sample Management
- Sample collection
- Material storage: reagent, reference material, test samples

SECOND DAY

Section 6: Immunogenicity & Immunology
- Basic immunology
- Immunogenicity for biologics, biosimilar, gene therapy and cell therapy.
- The different immune response

Section 7: Immunogenicity Assays
- ADA
- NAb
- Hypersensitivity and IgE testing

Section 8: Immunogenicity 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

Section 9: Assay Development
- Practical Considerations
- Positive Controls
- Definitions
- Interference – Signal Enhancement
- Interference – Signal Inhibition
- Topics for discussion
- Considerations for MAbs

Section 10: Regulatory Guidelines for Validation
- EMA guidance
- FDA guidance
- EMA draft guidance for monoclonal antibodies
- Health agencies immunogenicity findings

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

Section 12: Immunogenicity Assay Validation
- Validation parameters: comparing FDA and EMA guidance
- Cut Point
- Sensitivity
- System suitability controls
- Case studies

Section 13: Biosimilar
- Background
- PK
- ADA
- NAb