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2-Day In-Person Seminar

Method Development and Validation for Assays Supporting Testing of Biologics

By: **Gwen Wise-Blackman, Ph.D**, Principal Consultant, Gwen Wise-Blackman Consulting, LLC

Location: Orlando, FL | March 22-23, 2018

SPEAKER

Gwen Wise-Blackman, Ph.D, Principal Consultant, Gwen Wise-Blackman Consulting, LLC

Gwen Wise-Blackman, Ph.D., has 20 years of combined experience in Cell-Based Assays and Quality Systems. She has worked at DuPont Pharmaceuticals, Catalent Pharma Solutions (formerly Magellan Laboratories and Cardinal Health), and Salix Pharmaceuticals. She is currently Principal Consultant at Gwen Wise-Blackman Consulting. Her career focus has been in High-Throughput Screening, Cell-Based Assay Method Development and Validation, and Quality Assurance. Gwen has a Bachelor of Science degree in biology from M.I.T and a PhD in Pharmacology from UVa. She is a member of ASQ and AAPS.

LEARNING OBJECTIVES

- Understanding the different requirements for small versus large molecules
- Mapping appropriate timelines with decision points
- Designing, developing, optimizing, and validating key methods
- Potency methods, other release and stability methods
- Preclinical and clinical methods
- Use of DOE and statistical analysis
- Handling of critical materials
- Process monitoring concepts
- Assessment of orthogonal methods
- Assessing readiness for validation
- Defining the validation protocol with real-time capture of data analysis
- Maintaining quality through documentation

COURSE DESCRIPTION

Biologics continue to be a steadily growing component of the pharmaceutical industry. The advent of large molecule therapeutics requires a different perspective on the assays needed to support development through preclinical and clinical testing.

This 2-day seminar is designed to offer a broad overview of developing and validating a range of assay methodologies for biologics with specific key analysis of cell culture, assay variability, and DOE. Specifically, this seminar covers essential concepts related to cell-based potency methods, ELISA, and other methods supporting biologics.

In addition to potency methods this seminar addresses immunogenicity methods for preclinical and clinical studies. The format of the seminar offers an examination of current best practices as well as time to dissect examples of documentation with emphasis on beneficial systems to consider. Scientists who attend this 2-day seminar will gain knowledge that will be beneficial in helping to achieve well-controlled validated methods.

AGENDA

Day One (8:30 AM - 4:30 PM)

- **Registration Process: 8:30 AM – 9:00 AM**
- **Session Start Time: 9:00 AM**
- Overview of Biologics and Biotechnology
- Differences between small molecule and large molecule therapeutics
- Assays required for biologics
- Timelines
- Regulatory guidances
- GxP in biologics
- Analytical CMC methods and bioassays
- Assays supporting product development, release, and stability
- Portfolio of required assays
- Mechanism of action and potency methods
- Selection of potency-indicating method(s)
- Assay formats/platforms
- Consideration of reagents, endpoints, signal to background
- Standardizing cell culture procedures
- Understanding and managing assay variability
- Overview of feasibility to validation
- Early development - feasibility
- Use of DOE
- Involvement of statisticians
- Development and final development
- Optimizing the assays
- Validation of cell-based methods

Day Two (8:30 AM - 4:30 PM)

- Assays supporting preclinical and clinical studies
- Regulatory guidance
- Assay platforms
- Reagents, endpoints, signal to background
- Method development
- Assessing matrix effects
- Method optimization
- Validation parameters
- Incurred sample reanalysis
- Immunogenicity methods
- Screening methods
- Confirmatory methods
- Neutralizing antibody method
- Biomarker validation
- Written procedures (methods, protocols, SOPs)
- Analyst training
- Maintaining quality in-house and in outsourcing

WHO WILL BENEFIT

Below titles working in biopharmaceuticals, pharmaceuticals, natural products/botanicals will be benefited by attending this seminar:

- Validation Scientists
- QA/QC
- Regulatory Affairs
- Laboratory Managers
- Assay Development Specialists
- Statistician
- CMC Titles
- Bio Assay



Registration Form

Registration Information:

- **Register Online**. Use your American Express, Visa or MasterCard.
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Seminar Topic: Method Development and Validation for Assays Supporting Testing of Biologics

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The Largest GRC Advisory Network
www.complianceonline.com
2479 East Bayshore Road, Suite 200, Palo Alto, CA 94303
Ph: +1-888-717-2436 | Fax: +1-650-362-2367