ComplianceOnline Organizes 2-Day Training in Method Development & Validation for Assays Supporting Testing of Biologics

February 4-5, 2021 event will teach how to develop & validate assay methodologies for biologics with key analysis of cell culture, assay variability, and DOE.

Method Development and Validation for Assays Supporting Testing of Biologics

SAN JOSE, CA, USA, January 28, 2021 /EINPresswire.com/ -- 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 virtual seminar will gain knowledge that will be beneficial in helping to achieve well-controlled validated methods.

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

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: February 4-5, 2021 (9:00 AM to 5:00 PM EST)

Register by phone: Please call our customer service specialists at +1-888-717-2436 or email to customercare@complianceonline.com

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

About the Speaker:
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.

About ComplianceOnline.com:

ComplianceOnline is a leading provider of regulatory compliance training programs for companies and professionals in regulated industries. ComplianceOnline has successfully trained over 55,000 professionals from 15,000 companies to comply with the requirements of regulatory agencies. ComplianceOnline is headquartered in Palo Alto, California, and can be reached at http://www.complianceonline.com. ComplianceOnline is a MetricStream portal. MetricStream (www.metricstream.com) is a market leader in Enterprise-wide Governance, Risk, Compliance (GRC), and Quality Management Solutions for global corporations.

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