ComplianceOnline Announces Seminar on "Method Development and Validation for Assays Supporting Testing of Biologics".

"Method Development and Validation for Assays Supporting Testing of Biologics" Seminar has been added to ComplianceOnline.com's offering.

SAN JOSE, CA, UNITED STATES, June 14, 2021 /EINPresswire.com/ -- ComplianceOnline, the world's leading provider of training for regulated companies is hosting a seminar entitled 'Method Development and Validation for Assays Supporting Testing of Biologics.' The seminar will be held on June 24-25, 2021, and will be presented by Gwen Wise-Blackman, Ph.D., who has 20 years of combined experience in Cell-Based Assays and Quality Systems.

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 virtual 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 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

Who will Benefit:
Below titles working in biopharmaceuticals, pharmaceuticals, natural products/botanicals will benefit by attending this seminar:

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

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: June 24-25, 2021 (9:00 AM - 5:00 PM EDT)

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.

For more information on ComplianceOnline or to browse through our training programs, please visit our website.

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