ComplianceOnline Announces Virtual Seminar on Analytical Instrument Qualification and System Validation

"Analytical Instrument Qualification and System Validation" Seminar has been added to ComplianceOnline.com's offering.

Analytical Instrument Qualification and System Validation

SAN JOSE, CA, UNITED STATES, December 13, 2021 / EINPresswire.com/ -- ComplianceOnline, the leading provider of training for regulated companies, is organizing a 2-day virtual seminar on Analytical Instrument Qualification and System Validation. The seminar to be held on January 12-13, 2022 will be presented by Dr. Mark Powell.

The seminar is geared toward IT/IS managers and system administrators, QA managers and personnel, Laboratory managers and supervisors, Analysts, Validation specialists, Software developers, Regulatory affairs personnel, and Consultants.

Analytical equipment should be qualified, and computer systems should be validated to demonstrate suitability for their intended use. To be acceptable to regulatory authorities, electronic records must comply with 21 CFR Part 11, Annex 11 to EU GMPs and more recent data integrity guidance. Recent EU and FDA reports demonstrate that qualification, validation and electronic records are priority areas for inspection.

A large number of FDA warning letters and the frequency of EU enforcement action in these areas demonstrate that companies sometimes struggle to understand or implement the regulations.

This 2-day seminar guides attendees through equipment qualification, calibration and computer system validation processes from planning to reporting. It also explains regulatory requirements

in these areas, including EU and US GMPs, as well as data integrity guidance documents from national and international regulatory bodies.

The seminar not only ensures a full understanding of the regulations and guidelines for equipment and records but helps attendees to develop a risk-based approach to compliance. Interactive exercises will be dispersed into and between the presentations.

Learning Objectives presented in the event overview include:

- Learn about the regulatory background and requirements for equipment qualification according to USP <1058> and computer system validation according to GAMP 5
- Be able to explain the difference between equipment calibration, qualification and system validation
- Learn which equipment/systems need to be qualified or validated
- Be able to allocate equipment and systems to USP <1058> and GAMP 5 categories and to design and execute qualification/validation protocols accordingly
- Understand the logic and principles of instrument qualification and system validation from planning to reporting
- Be able to develop a qualification and validation strategy
- Understand how to archive raw data from hybrid systems: electronic vs. paper
- Be able to define and demonstrate regulatory compliance to auditors and inspectors
- Be able to develop inspection-ready documentation
- Learn how to ensure, document and audit the integrity of GMP records

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: January 12-13, 2022 (10:00 AM to 5:00 PM EST)

About the Speaker:

Dr Mark Powell is a Fellow of the Royal Society of Chemistry (RSC) with over thirty years' experience as an analytical chemist. Mark was Honorary Treasurer of the RSC's Analytical Division and led a working group on continuing professional development until July 2016, when his term of office ended. Between 2003 and 2013, he was the Analytical Development Manager, and later Scientific Manager, of a UK-based contract research organization which specialized in early-stage oral drug development. During this time, he was responsible for method validation, verification and transfer activities, as well as the qualification of laboratory instruments and computerized data systems. In 2013, he set up Mark Powell Scientific Limited, which provides training and consultancy services to pharmaceutical companies. Mark has since enjoyed working with companies of all sizes around the world on a variety of training and consultancy assignments, and has recently co-authored a White Paper on Pharmaceutical Data Integrity for the laboratory supply company VWR.

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 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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