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.

SAN JOSE, CA, UNITED STATES, June 18, 2021 /EINPresswire.com/ -- ComplianceOnline, the world's leading provider of training for regulated companies is holding a seminar entitled 'Analytical Instrument Qualification and System Validation.' The seminar will be held on July 12-13, 2021, and will be presented by Dr. Mark Powell who has over thirty years of experience as an analytical chemist.

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 course 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 course 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:
• 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

Who will Benefit:
• IT/IS managers and system administrators
• QA managers and personnel
• Laboratory managers and supervisors
• Analysts
• Validation specialists
• Software developers
• Regulatory affairs
• Training departments
• Documentation departments
• Consultants

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: July 12-13, 2021 (10:00 AM to 5:00 PM EDT)

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 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.

Priyabrata Sahoo
ComplianceOnline
+1 888-717-2436
email us here
Visit us on social media:
Facebook
Twitter
LinkedIn