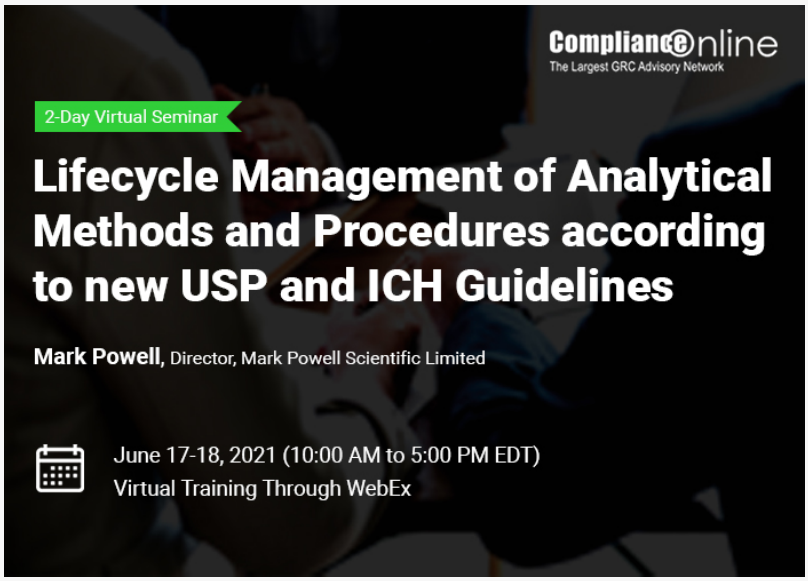
Lifecycle Management of Analytical Methods & Procedures according to new USP & ICH Guidelines: ComplianceOnline Seminar

"Lifecycle Management of Analytical Methods and Procedures according to new USP and ICH Guidelines" Seminar has been added to ComplianceOnline.com's offering.



SAN JOSE, CA, UNITED STATES, June 7, 2021 /EINPresswire.com/ -- ComplianceOnline, the world's leading provider of training for regulated companies will be holding a 2-day virtual seminar entitled 'Lifecycle Management of Analytical Methods and Procedures according to new USP and ICH Guidelines.' The seminar will be held on June 17-18, 2021, and presented by Dr. Mark Powell, a Fellow of the Royal Society of Chemistry (RSC) with over thirty years of experience as an analytical chemist.

Results of analytical methods are used as the basis for important decisions during the development and manufacturing of pharmaceutical products. All regulatory agencies expect the regulated industry to have procedures in place to ensure suitable levels of reliability, accuracy, and precision of such methods. The procedures should cover lifecycle phases from design, development, validation to ongoing routine use.

Managing analytical methods and procedures according to the lifecycle approach has been recommended in recent FDA guidance documents and stimuli articles published by the USP. For example, the recent FDA guidance "Analytical Procedures and Methods Validation for Drugs and Biologics" contains a section on Lifecycle Management of Analytical Procedures.

This 2-day workshop will explain the background to the new Analytical Procedure Lifecycle guidelines and give attendees the knowledge needed to implement recommended approaches. Interactive exercises will be included in the workshop.

Learning Objectives:

- Learn about the regulatory background and recommendations for managing the lifecycle of analytical methods and procedures
- Understand current and future industry trends: the concept of lifecycle management of analytical methods, recent ICH guidance (ICH Q12), proposed USP General Chapter <1220> (Analytical Procedure Lifecycle) and Quality by Design (QbD) principles for method development and validation
- Learn how to plan, execute and document design, development and validation of methods developed in-house
- Understand the principles of lifecycle management for compendial procedures and for managing method transfer
- Be able to develop a strategy for analytical procedure lifecycle management
- Understand risk management strategies throughout the procedure lifecycle
- Understand the concept of measurement uncertainty
- Be able to justify and document decisions about type and extend of revalidation after method changes
- Be able to define and demonstrate FDA, EU, USP and ICH compliance to auditors and inspectors
- Be able to develop inspection-ready documentation during on-going routine operation
- Understand what questions will be asked during audits and inspections and how to answer them

Who Will Benefit:

- QA managers and personnel
- Quality control scientists
- Method development scientists
- Analytical chemists
- Validation specialists
- Laboratory managers and supervisors
- Regulatory affairs professionals
- Training departments
- Documentation departments
- Consultants

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: June 17-18, 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 of

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 that 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.

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