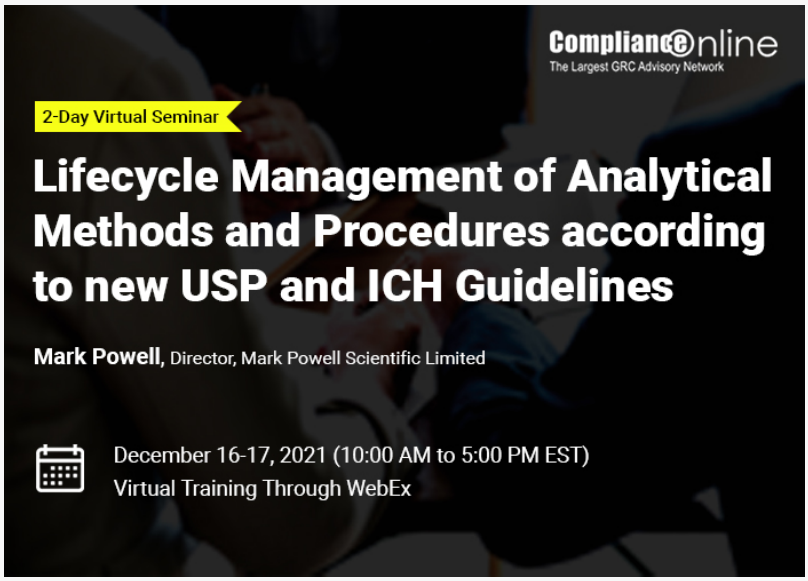
Lifecycle Management of Analytical Methods & Procedures According to New USP & ICH Guidelines – ComplianceOnline Seminar

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



Lifecycle Management of Analytical Methods and Procedures according to new USP and ICH Guidelines

SAN JOSE, CA, UNITED STATES, November 29, 2021 / EINPresswire.com/ -- ComplianceOnline, the leading provider of training for regulated companies, today announced the company will host a 2-day virtual seminar about Lifecycle Management of Analytical Methods and Procedures according to new USP and ICH Guidelines.

Results of analytical methods are used as the basis for important decisions during 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 on-going 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.

The seminar 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.

Attendees to the seminar will:

•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

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: December 16-17, 2021 (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.

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

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