ComplianceOnline Announces Seminar on Validation, Verification and Transfer of Analytical Methods

"Validation, Verification and Transfer of Analytical Methods (Guidelines from FDA/EMA, USP and ICH)" Seminar has been added to ComplianceOnline.com's offering.

SAN JOSE, CA, USA, March 15, 2021 /EINPresswire.com/ -- ComplianceOnline, the largest GRC network, has organized a seminar on the topic 'Validation, Verification, and Transfer of Analytical Methods' to provide an understanding of implementing guidelines from FDA/EMA, USP, and ICH to Laboratory Personnel. The event will be held on March 25-26, 2021 (10:00 AM to 5:00 PM EDT) and will be presented by Dr. Mark Powell, Director, Mark Powell Scientific Limited.

Analytical methods used for GxP purposes should be validated to ensure the reliability, consistency and accuracy of analytical data. Compendial methods should be verified to demonstrate the suitability of laboratories to successfully run the method and when methods are transferred between laboratories successful transfer should be demonstrated through testing or a transfer waiver, if justified. If a laboratory uses an alternative method instead of a compendial method, equivalence or superiority of the alternative method should be demonstrated.

Recent guidance on method validation and transfer has been produced by FDA and EMA, and USP has guidance chapters on method validation, verification and transfer, equivalence testing and statistical evaluation. Articles in US Pharmacopeial Forum have introduced the concepts of measurement uncertainty and lifecycle management for analytical procedures. Lifecycle management has also been the subject of recent FDA and ICH publications.

This 2-day seminar will help attendees to understand regulatory requirements for method

validation, verification and transfer. It will also suggest ways to de-risk the method validation process through prior evaluation of method performance and the use of effective protocols.

Learning Objectives:
- Understand the regulatory requirements for validation of analytical methods.
- Learn how to plan, execute and document development and validation of in-house methods.
- Be able to explain the different requirements for validation, verification and transfer of analytical procedures.
- Understand the principles of validation of in-house methods, verification of compendial methods and method transfer.
- Know how to demonstrate equivalence to compendial methods.
- Understand the important qualities of stability-indicating methods.
- Be able to select test parameters, test conditions and acceptance criteria for different analytical measurements.
- Know how to plan, justify, and document revalidation after method changes.
- Understand important indicators of the suitability of a method for routine QC use.
- Understand approaches for the statistical evaluation of validation test results.
- Understanding what questions will be asked during audits and inspections and how to answer them.

Who will Benefit:
- Quality assurance personnel
- Quality control and method development analysts
- Validation specialists
- Laboratory managers and supervisors
- Regulatory affairs personnel
- Consultants

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: March 25-26, 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

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