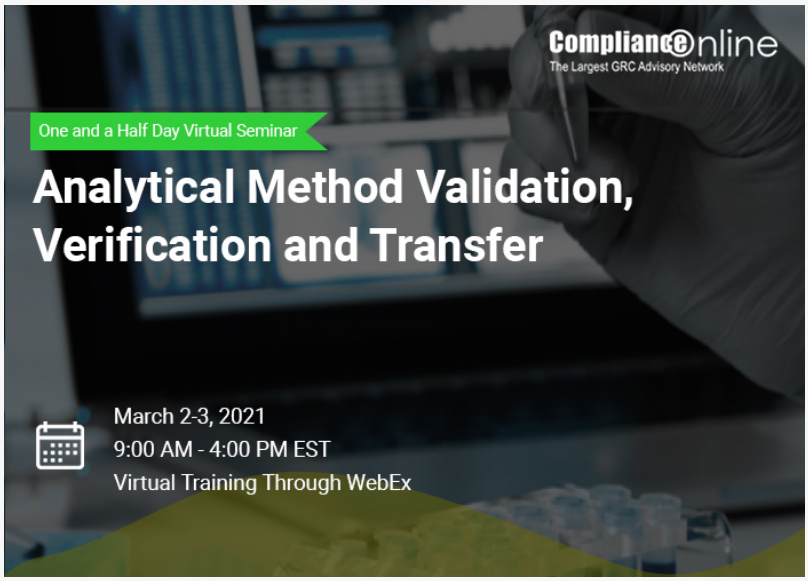
Analytical Method Validation, Verification, and Transfer - Upcoming Seminar Hosted by ComplianceOnline

"Analytical Method Validation, Verification and Transfer" Seminar has been added to ComplianceOnline.com's offering.



Analytical Method Validation, Verification and Transfer

SAN JOSE, CA, USA, February 24, 2021 /EINPresswire.com/ -- ComplianceOnline has officially launched registration for the 'Analytical Method Validation, Verification and Transfer' Seminar with Kelly Thomas, Vice President, Americas Quality Operations at Stallergenes Greer. The seminar will be held on March 2-3, 2021 (9:00 AM - 4:00 PM EST).

Reliable analytical results are necessary to make informed decisions about the quality and safety of the products in the pharmaceutical industry. Also, such analytical data are required for regulatory submissions in support of the drug product registrations. Therefore, meaningful experimental designs including system suitability parameters must be planned for the intended use of the procedure.

In this course, the general guideline for the determination of the analytical characteristics for different types of validation procedures is highlighted for the analysis of both the drug substance and drug product. The factors to consider for verification of the compendial procedures will also be discussed. Also, different approaches for the transfer of analytical procedure from one lab (transferring) to other labs (s) (receiving) under different circumstances will be covered. Other related topics for obtaining reliable data will also be discussed. These topics include analytical instrument qualification as well as how to set, handle and monitor specifications.

Due to the global nature of the pharmaceutical industry, other quality topics on both regulatory (ICH) and compendial (USP) harmonization are also covered. These topics are valuable for

scientists directly or indirectly involved with drug development, analysis. stability studies or regulatory/compendial submissions.

Learning Objectives:
- Drug Approval Process and Regulatory Requirements (private standards)
- Pharmacopeias and Compendial Approval Process (public standards)
- Compendial Harmonization Process
- Chromatography System Suitability Requirements
- Allowed Adjustments of Chromatographic System Parameters
- Analytical Instrument Qualifications including DQ, IQ, OQ, PQ
- Analytical Method Validation
- Analytical Method Verification
- Analytical Method Transfer
- Alternative to Official procedure and options
- Analytical Procedure Life Cycle
- How to Set Specifications and how to handle out-of-specification (OOS) and out-of-trend (OOT) results

Who will benefit:
Pharmaceutical Industry, Contract Laboratories (CRO), government (FDA or regulatory authorities), Academia (pharmacy, Pharmaceutical, Chemistry)
- Analytical/Chemists
- Formulation Chemists
- Lab Supervisors and Managers
- QC Managers and Personnel
- QA Managers and Personnel
- Regulatory Personnel
- Compendial Liaisons
- Pharmaceutical scientist/Pharmacists working in Industry
- Senior or Graduate students (chemistry, pharmaceutical, pharmacy)

Course Background:

This course is based on a recent book entitled "Pharmaceutical Analysis for Small Molecules" by Dr. Davani which was published by Wiley in 2017. Also, examples and case studies will be provided based on insights and extensive experience in developing and implementing these topics in industry/pharmacopeia. Guidance and advice will also be provided based on interactions with the global pharmaceutical industry, FDA, and other regulatory authorities worldwide.

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: March 2-3, 2021 (9:00 AM - 4:00 PM EST)

Speaker:
Ms. Thomas has over two decades of cGMP hands-on industry experience in both pharmaceutical and medical device manufacturing operations. Her experience covers all Quality Systems; as well as, all areas of validation; including, process/product validation, facilities validation, CSV and 21 CFR Part 11, test method validation, equipment/automated processes, and cleaning validation.
Utilizing strategic thinking, risk-based approaches, and Lean principles, she has demonstrated success in steering and managing complex projects within the pharmaceutical and medical device industries.

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:
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