2-Day Virtual Seminar: Reduce Costs for Compliance with Data Integrity: 21 CFR Part 11, SaaS/Cloud, EU GDPR

ComplianceOnline.com is hosting a Seminar entitled 'Reduce Costs for Compliance with Data Integrity: 21 CFR Part 11, SaaS/Cloud, EU GDPR' with David Nettleton.

SAN JOSE, CA, USA, January 21, 2021 /EINPresswire.com/ -- The "Reduce Costs for Compliance with Data Integrity: 21 CFR Part 11, SaaS/Cloud, EU GDPR" conference has been added to ComplianceOnline.com's offering.

This highly interactive two-day course uses real life examples and explores proven techniques for reducing costs, usually by two-thirds, associated with implementing, and maintaining computer systems in regulated environments.

• It details the requirements for Part 11 and Annex 11: SOPs, software product features, infrastructure qualification, and validation.
• The instructor addresses the latest computer system industry standards for data security, data transfer, audit trails, electronic records and signatures, software validation, and computer system validation.
• Understand the specific requirements associated with local and SaaS/cloud hosting solutions.
• Nearly every computerized system used in laboratory, clinical, manufacturing settings and in the quality process has to be validated. Participants learn how to decrease software implementation times and lower costs using a 10-step risk-based approach to computer system validation.
• The instructor reviews recent FDA inspection trends and discusses how to streamline document authoring, revision, review, and approval.
• Participants will learn how to write a Data Privacy Statement to comply with the EU General Data Protection Regulation (GDPR).
• This course benefits anyone that uses computer systems to perform their job functions and is

ideal for professionals working in the health care, clinical trial, biopharmaceutical, and medical device sectors. It is essential for software vendors, auditors, and quality staff involved in GxP applications.

Learning Objectives:

• Reduce costs, usually by two-thirds, for compliance with electronic records
• Learn how to use electronic records and electronic signatures to maximize productivity
• Understand what is expected in Part 11 and Annex 11 inspections so you are prepared
• Avoid 483 and Warning Letters
• Understand the responsibilities and specific duties of your staff including IT and QA
• Understand your responsibilities and liabilities when using SaaS/cloud
• Learn how to perform risk-based Computer System Validation using fill-in-the-blank templates
• How to select resources and manage validation projects
• "Right size" change control methods that allows quick and safe system evolution
• Minimize validation documentation to reduce costs without increasing regulatory or business risk
• Learn how to reduce testing time and write test cases that trace to elements of risk management
• Learn how to comply with the requirements for data privacy
• Learn how to buy COTS software and qualify vendors
• Protect intellectual property and keep electronic records safe

Who will Benefit:

• GMP, GCP, GLP, regulatory professionals
• QA/QC
• IT
• Auditors
• Managers and directors
• Software vendors, SaaS hosting providers

About the Speaker:

Computer System Validation’s principal, David Nettleton is an industry leader, author, and teacher for 21 CFR Part 11, Annex 11, HIPAA, software validation, and computer system validation. He is involved with the development, purchase, installation, operation and maintenance of computerized systems used in FDA compliant applications. He has completed more than 230 mission critical laboratory, clinical, and manufacturing software implementation projects. His most popular book is Risk Based Software Validation - Ten easy Steps, which provides fill-in-the-blank templates for completing a COTS software validation project.

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 or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: January 27-28, 2021 (9:00 AM - 3:00 PM PST)

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