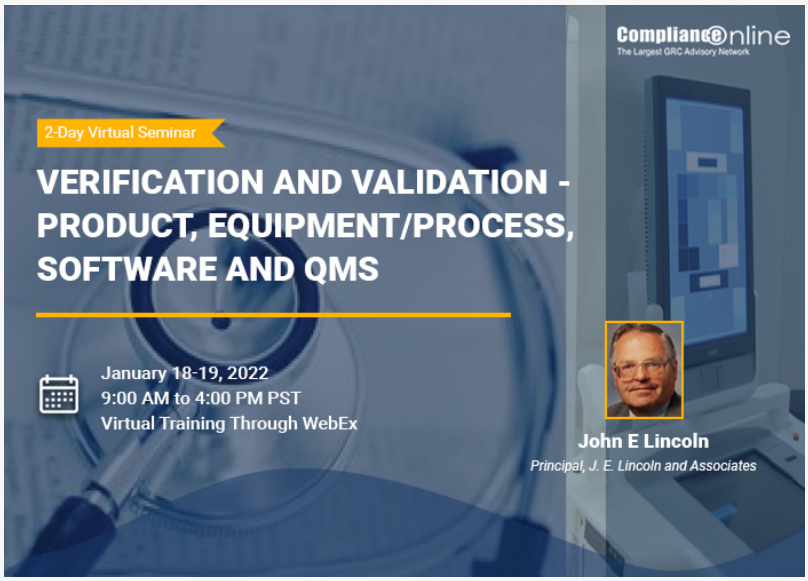
# Seminar on Verification and Validation - Product, Equipment/Process, Software and QMS

*"Verification and Validation - Product, Equipment/Process, Software and QMS" Seminar has been added to ComplianceOnline.com's offering.*

SAN JOSE, CA, UNITED STATES, December 15, 2021 / EINPresswire.com/ -- ComplianceOnline, the leading provider of training for regulated companies, is hosting a two-day virtual seminar on Verification and Validation - Product, Equipment/Process, Software, and QMS. The Seminar to be held on January 18-19, 2022, will be presented by John E. Lincoln.



Verification and Validation - Product, Equipment/Process, Software and QMS

This seminar will provide valuable assistance to all regulated companies that need to review and modify their Master Validation Planning and Plan(s). While this information is focused on Medical Devices, its principles apply to personnel/companies in the Pharmaceutical, Diagnostic, and Biologics fields.
One major failing with regulated companies is the lack of sufficient or targeted risk-based V&V planning. The seminar will help attendees Develop/review a company's Master Validation Plan for major cGMP deficiencies and address the U.S. FDA's newer and tougher regulatory stance.

Learning Objectives as presented in the event overview:

- Understand Verification and Validation, differences and how they work together
- Develop a “Working Definition” of V&V, Qualification, and related terms
- Discuss recent regulatory expectations
- How to document a “risk-based” rationale, and use it in a resource-constrained environment
- Determine key “milestones” and “tasks” in a project; device sample provided
- Locate and document key subject “inputs”

- Compile “generic” Master and Individual Validation Plans
- Learn the key element of a Product V&V File / Protocol
- How to develop Process and/or Production / Test Equipment V&V Files / Protocols
- Basic Test Case / Script construction
- Sample sizes and their justification
- Learn the key 11 elements of Software V&V expected by the FDA and how to document
- See how to compile QMS Electronic Records and Electronic Signatures V&Vs per 21 CFR 11 and related CGMPs

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: January 18-19, 2022 (9:00 AM to 4:00 PM PST)

About the Speaker:

John E. Lincoln, is Principal of J. E. Lincoln and Associates LLC, a consulting company with over 36 years’ experience in U.S. FDA-regulated industries, 22 as a full-time consultant. John has worked with companies from start-up to Fortune 100, in the U.S., Mexico, Canada, France, Germany, Sweden, China and Taiwan. He specializes in quality assurance, regulatory affairs, QMS problem remediation and FDA responses, new / changed product 510(k)s, process / product / equipment including QMS and software validations, ISO 14971 product risk management files / reports, Design Control / Design History Files, Technical Files. He's held positions in Manufacturing Engineering, QA, QAE, Regulatory Affairs, to the level of Director and VP (R&D). In addition, John has prior experience in military, government, electronics, and aerospace. He has published numerous articles in peer reviewed journals, conducted workshops and webinars worldwide on CAPA, 510(k)s, risk analysis / management, FDA / GMP audits, validation, root cause analysis, and others. John is a graduate of UCLA.

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.

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