Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Verification vs. Validation - Product Process Software and QMS

Las Vegas, NV

September 29th & 30th, 2016

9:00 AM to 6:00 PM

Price

(Without Stay) Price: **$1,295.00**

(Seminar for One Delegate)

(With Stay) Price: **$1,695.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees (With stay)

Price: **$4,323.00** You Save: $4,152.0 (49%)*

~~$8,475.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

John E Lincoln

Consultant, Medical device and Regulatory affairs

John E Lincoln is Principal of J. E. Lincoln and Associates LLC, a consulting company. John, a graduate of UCLA, is a medical device and Regulatory Affairs consultant. He has helped companies to implement or modify their GMP systems and procedures, product risk management and U.S. FDA responses. In addition, he has successfully designed, written and run all types of process, equipment and software qualifications/validations, which have passed FDA audit or submission scrutiny, and have been described in peer-reviewed technical articles and workshops worldwide.

Overview :

This course will review the company Master Validation Plan for major key inputs and CGMP deficiencies. It will address the FDA's newer and tougher regulatory stance. This course's aim is to prove "Product Risk Based V&V" by sufficient, targeted and documented risk-based V&V test case elements/scripts. It will teach participants to evaluate its elements against ISO 14971 and ICH Q9 for hazard analysis and product risk management.

This course will evaluate different field-tested, U.S. FDA-reviewed V&V protocols; how to employ equipment/process Requirements Specs / DQs, IQs, OQs, and PQs, or their equivalents per ASTM E2500, all against a background of limited company resources.

Seminar Pricing Includes (With Stay)

- Samsung Galaxy Tab 4
- 2 Days Stay
- Pick-up and Drop Facility (Nearest Airport)
- Break-Fast and Lunch
- High Tea
- Pack of 3 Webinars will be provided which has been done in the past on similar subject

Agenda:

Day One

Lecture 1 : Master Validation Planning and the Master Validation Plan(s)

Lecture 2 : HProduct, Process / Equipment Hardware V&V

Lecture 3 : Product / Device V&V

Lecture 4 : Software V&V

Lecture 5 : Quality Management System / 21 CFR Part 11 V&V

Lecture 6 : OSummary of morning discussion

Lecture 7 : BGroup activity on the MVPs

Lecture 8 : CReview of group activity and Q&A

Day Two

Lecture 1 : Software V&V documentation "model"

Lecture 2 : Software V&V protocols - "black box", "white box"

Lecture 3 : Electronic Records and Electronic Signatures (Part 11)

Lecture 4 : Summary of morning discussion

Lecture 5 : Group activity on 1) hardware / equipment, and 2) software V&V protocols

Lecture 6 : Review of group activity and Q&A

Lecture 7 : Course summary discussion

Lecture 8 : Summary of morning discussion

Lecture 9: Group activity on the MVPs

Lecture 10: Review of group activity and Q&A

Why should you attend:

- This session helps participants:
- Understand Verification and Validation, differences and how they work together;
- Discuss recent regulatory expectations;
- Know how to document a "risk-based" rationale, and use it in a resource-constrained environment;
- Determine key "milestones" and "tasks" in a project;
- Locate and document key subject "inputs";
- Compile "generic" Master and Individual Validation Plans;
- Learn the key element of a Product V&V File/Protocol;
- Understand how to develop Process and/or Production/Test Equipment V&V Files/Protocols;
- Get a grasp of basic Test Case construction;

Who Will Benefit:

- Senior and middle management and staff
- Regulatory Affairs
- Quality Assurance or Quality Control Professionals
- QA/QC
- IT/IS
- R&D
- Production Management
- Manufacturing Engineers
- Process Engineers
- Software Engineers
- Project Managers
- Hardware and software vendors, sales and marketing

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
4. Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals

Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

GlobalCompliancePanel