Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Validation of Computer Systems for Production and Quality and Software Embedded Medical Devices

Baltimore, MD

September 21st & 22nd, 2017

9:00 AM to 6:00 PM

Price

Price: **$1,295.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$3,885.00** You Save: $2,590.0 (40%)*

~~$6,475.00~~

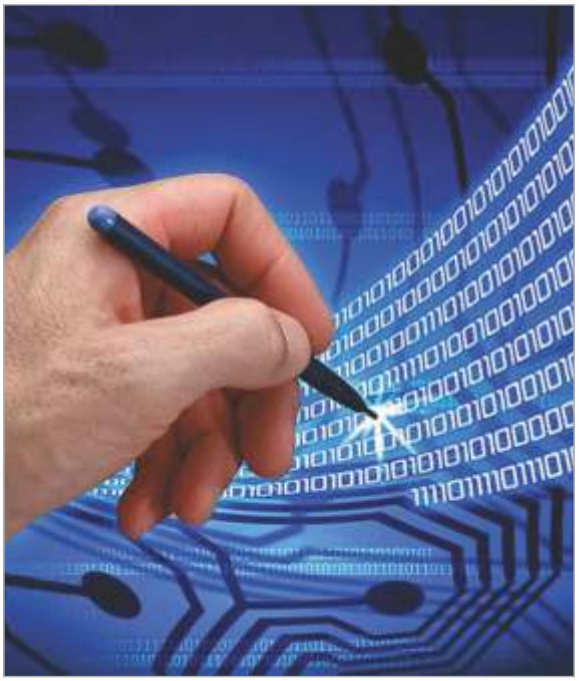
ENROLL

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

David R. Dills

Global Regulatory Affairs & Compliance Consultant

David R. Dills, Global Regulatory Affairs & Compliance Consultant currently provides regulatory affairs and compliance consultative services for early-stage and established Class I/II/III device, IVD, biopharmaceutical, cosmetics and nutraceutical manufacturers on the global landscape, and has an accomplished record with more than 27 years of experience in the areas of Regulatory Affairs, Compliance and Quality Systems. He has been previously employed, with increasing responsibilities by device manufacturers and consultancies, including a globally recognized CRO and has worked directly with manufacturers engaged in compliance remediation activities involving consent decrees, CIA's, warning letters, and customer generated compliance events, conducts QS, regulatory, compliance assessments/audits and FDA Mock Inspections for State of Readiness.



Why should you attend:

- 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
- Software Verification & Validation requirements of the FDA and ISO.
- The latest FDA Software Guidance & Regulations, including Part 11 -impact on V&V strategies
- Device and Manufacturing software requirements for V & V

Agenda:

Day One

- Introductions and Overview
- Device Concepts, Software Requirements
- Software Designs and Implementation Activities
- Software Testing
- Non-Device Validation
- Software development life cycle (SDLC), including examples of commonly used SDLCs
- Software V&V documentation
- Electronic Records and Electronic Signatures (Part 11)
- Software Embedded Medical Device Testing and Validation and Regulatory Expectations and Requirements
- Software Standard Operating Procedures related to V&V
- Software Quality Assurance Planning
- Software Test Strategies & Methodologies
- Requirements Validation
- Verification and validation, including regulatory definitions, regulatory intent, and common tasks
- Regulatory framework and the relationship of various sources of regulatory requirements
- Key regulations, standards, and guidance documents
- Integrating risk management processes
- Design control and software validation guidance
- Testing-level strategies (unit, integration, system, user)
- Methods development and documentation requirements, plus test protocol content
- Configuration management, change management, and maintenance strategies
- Documentation requirements for premarket submissions
- Processes, procedures, and outputs for typical phases (e.g., examples, roles, relationships)
- Defects and issues management
- Design and quality planning, including traceability and reviews
- Lessons learned from case studies and warning letters
- Design software validation plans that build confidence in the software and comply with regulatory requirements for device, commercial off-the-shelf, and Quality System software
- Use risk management to focus validation activities to minimize risk
- Streamline elements of the Quality System for cost-efficient software development and validation

Day Two

- Recap of Day 1
- Regulatory Guidance and Regulations and Additional Resources
- Select appropriate lifecycle models and synchronize validation activities for all types of software
- Write unambiguous, testable requirements
- Integrate best development engineering practices to support validation efforts
- Organize test designs, test cases, and test procedures that effectively cover requirements being verified, and that provide opportunities for review and management of the process
- Regulatory and Compliance Overview/FDA Snapshot on V&V for Manufacturers/Master Validation Planning
- FDA's approach and Risk Management Tools with ISO 14971, ICH and other Guidance/Standards - Product, Process Equipment V&V Product/Device V&V
- Software V&V and where and how does software validation integrate into the Validation Plan
- Quality Management System/21 CFR Part 11 expectations and requirements
- Avoid or Minimize Compliance Concerns and Issues: Q&A/FAQs and review of company documentation
- Review of group activity and hands-on examples and activities show real-world implementation of useful governing principles, tools and templates and the most recent enforcement actions for trending, compliance and governance

Debrief/Adjourn

- Recap of topics and key discussion points and take away message
- FAQs and latest trends with industry and regulators

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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
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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

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