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

Date : Sep 21, 2017 - 09:00 AM - Sep 22, 06:00 PM

Event URL : http://www.nyeventslist.com/events/validation-of-computer-systems-for-production-and-quality-and-software-embedded-1495204867

Organizer : Global Compliance Panel

Venue :

Location : DoubleTree by Hilton Baltimore - BWI Airport 890 Elkridge Landing Rd, Linthicum Heights, MD 21090, USA,
Baltimore, MD, US, ZIP: 21090
Phone: 1 929 900 1853

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
- How to determine & demonstrate an appropriate V & V strategy
- How to determine & handle software for different Levels of Concern
- What V&V is required for 3rd Party software-custom and Off-the-shelf
- Impact of FDA, Mobile APPS, Cyber Security, and software standards such as IEC 62304
- What to look for during software vendor audits.
- V & V documentation and level of detail required for device submissions.
- How to document a "risk-based" rationale, and use it in a resource-constrained environment
- Determine key "milestones" and "tasks" in a project as well as discussing audience related projects for discussion points
- Generate Master and Individual Validation Plans
- Learn the key elements of a Product V&V protocol and expectations with the Summary Report
- Develop Process and/or Production/Test Equipment V&V Files/Protocols
- Sample sizes and their justification
- Learn the key elements of Software V&V expected by the FDA and how to document appropriately and adequately
- QMS Electronic Records and Electronic Signatures per 21 CFR 11
- Regulatory Requirements for Software Validation and Benefits

- Quality System Regulation vs Pre-Market Submissions
- Software requirements in specifications
- Verification and Validation process
- IQ/OQ/PQ in software V&V and next steps for compliance
- Software development as part of system Design
- Software life cycle verification
- Software validation after a change
- Validation of Off-the-Shelf Software and Automated Equipment
- What is Process Validation
- What are FDA and international requirements for Process Validation
- Process Validation & Equipment Qualification
- Examples of successful Process Validation activities
- Where and how does software validation integrate into the Validation Plan
- Recent examples of FDA Warning Letter cites and other enforcement actions for non-compliant V&V findings...what went wrong
- Seminar attendees are encouraged to bring examples of their work from the functional area on the various topics as applicable for group discussion
- Review and discuss pain points, challenges and solutions
- Guidance for Industry, Trends and FDA Inspection & Enforcement Statistics and Trends
- Prepare for Regulatory Inspections, including FDA and Operate in a State of Readiness

Who will benefit:

This seminar will provide an overview and in-depth snapshot of the process for managing V&V activities affecting product, process, equipment and the QMS. Company employees responsible for new product development, regulatory submissions, initiating/overseeing company-wide V&V planning, using a risk-justified approach and responsible for some of the areas identified herein, certainly will benefit. Employees who will benefit include all levels of management and departmental representatives from key functional areas and those who desire a better understanding or a "refresh" overview of the V&V process with product, process, software and impact on the QMS from start to finish, with key emphasis on regulatory compliance and governance, including:

- Regulatory Affairs Management
- Regulatory Affairs Specialist
- Auditors
- Compliance
- Quality Assurance Management
- Engineering/Technical Services
- Operations/Manufacturing
- Consultants
- Quality Assurance or Quality Control Professionals
- IT/IS
- R&D
- Production Management
- Manufacturing Engineers
- Process Engineers
- Software Engineers
- Validation Engineers
- Project Managers
- Hardware and software vendors, sales and marketing

Please contact the event manager Marilyn below for the following:

www.nyeventslist.com

- For Registrations Please call +1 929.900.1853
- Discounts for registering 5 or more participants.
- If you company requires a price quotation.
Event Manager Contact: marilyn.b.turner(at)nyeventslist.com
You can also contact us if you require a visa invitation letter, after ticket purchase.
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