SAN FRANCISCO
EVENTS LIST

Validation and 21 CFR Part 11 Compliance of Computer Systems

Date : Mar 01, 2018 - 09:00 AM - Mar 02, 06:00 PM

Event URL : http://www.sfbayeventslist.com/events/validation-and-21-cfr-part-11-compliance-of-computer-systems-mar-2018

Organizer : GlobalCompliancePanel

Venue :

Location : 407, Squire Rd
Revere, MA, USA, ZIP: 02151

Computer Systems Validation (CSV) also known as Software Validation is all-pervasive in the Life Sciences Industry. It is a requirement of all the predicate rules, as well as 21 CFR 11 and Annex 11. However, unless one knows how to implement CSV, it is often very hard to detect the requirement for CSV, and very hard to determine what needs to be done, to meet domestic and / or international regulations or business continuity requirements. In addition, the FDA has stepped up 21 CFR 11 inspections that include CSV.

This course will build on the Validation and 21 CFR 11 Compliance Basic Course, to give hands on experience on executing on the computer systems validation of a system, and to discuss related activities such as Validation Master Plan, Infrastructure Qualification, Project Management for Validation and Validation of Test Tools

The Seminar

This hands-on course will provide the attendees with more detailed experience on validation / 21 CFR 11 compliance of a computer system, as well as details for activities associated with computer systems validation as follows:

1. Validation Master Plan
2. Complete Validation for a System
3. Excel Spreadsheet Validation
4. Change Control

5. SOPs
6. Test Tools Validation
7. Project Management for Validation

Who Should Attend:

- VP of IT
- Director of IT
- Quality Managers
- Project Managers (for CSV / IT)
- Validation Specialists
- Database Administrators
- System Administrators
- Directors / Senior Directors of Discovery
- Directors / Senior Directors of Development
- Directors / Senior Directors of Commercialization
- Document Managers
- Training Managers

Industries:

- Pharmaceuticals
- Biotech
- Medical Device
- Radiological Health
- Blood Products
- Companion Animals
- Food
- Cosmetics
- Tobacco
- Academia

Day 1 Schedule

Lecture 1:
Introduction/Background

- Introductions / Participants' Understanding
- Participants' Objectives for the Course (Please come prepared to discuss)

Lecture 2:
Requirements at a High Level

- Types of Requirements
- Difference between User Requirements & Functional Requirements

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Lecture 3:
Detailed Requirements Study

- Gathering Requirements
- Entity Relationship Diagram
- Process Decomposition
- Risk Assessment for Requirements
- Exercise on how to create Requirements

Lecture 4:
Design

- Design Specifications
- Software Configuration and Build
- Exercise on how to create Design Specifications

Day 2 Schedule

Lecture 5:
CSV Detailed Study (Cont'd)

- Traceability Matrix
- Verification and Testing
- Exercise Creating Validation Scripts
- Exercise Creating Traceability Matrix

Lecture 6:
Other Documents

- Validation Plan
- Test Protocols
    - Test Reports
- Validation Report
- Validation Registry

Lecture 7:
Special Topics

- Project Management for CSV

- Infrastructure for CSV
- Selecting software for 21 CFR 11 Compliance
- Test Tools for CSV

Lecture 8:
Change Control & Business Continuity

- Change Control
- Implementing Business Continuity for CSV

Angela Bazigos

CEO, Touchstone Technologies Silicon Valley

Seasoned Executive with 40 years of experience in the Life Sciences & Healthcare Industries. Positions include Chief Compliance Officer http://morflearning.com/angelabazigos/. Experience combines Quality Assurance, Regulatory Compliance, Business Administration, Information Technology, Project Management, Clinical Lab Science, Turnarounds and Business Development. Past employers / clients include Roche, Novartis, Genentech & PriceWaterhouseCoopers. Co-authored & prototyped 21 CFR 11 guidance with FDA. Co-authored Computerized Systems in Clinical Research w/ FDA http://www1.diahome.org/~/media/4FA562336EBD46C58CDC43A8B7773095.ashx Patent on speeding up software compliance https://www.google.com/patents/US8266578. Recently quoted in Wall Street Journal for using training to bring regulatory compliance to the Boardroom http://blogs.wsj.com/riskandcompliance/2015/07/24/using-training-to-bring-compliance-to-boardrooms/ National Trainer for Society of Quality Assurance. Comments / collaborates with FDA on new guidance documents. Former President of Pacific Regional Chapter of Society of Quality Assurance. Stanford's Who's Who for LifeSciences: http://www.stanfordwhoswho.com/Angela.Bazigos.7144112.html#overview.

Please contact Marilyn Turner: Phone: +1 929 900 1853 Email: marilyn.turner [a] nyeventslist.com for registrations

Event Categories :