Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Validation and Part 11 Compliance of Computer Systems and Data

Zurich, Switzerland

December 1st and 2nd, 2016

9:00 AM to 6:00 PM

Price

(Without Stay) Price: **$1,695.00**

(Seminar for One Delegate)

(With Stay) Price: **$2,095.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees (With stay)

Price: **$5,343.00** You Save: $5,132.0 (49%)*

~~$10,475.00~~

ENROLL

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

Ludwig Huber

Chief Advisor -
Global FDA compliance, Labcompliance

- Chairman, presenter and panel discussion member at US-FDA Industry Training sessions and conferences
- Served as team member of PDA's task forces "21 CFR Part 11", of US-FDA internal documents, and of the GAMP® special interest group on Laboratory Systems.
- Presenter of the Year of the Institute for Validation and Technology
- Director and chief editor of www.labcompliance.com, the global on-line resource for validation and compliance issues for laboratories.

Overview :

Analytical and other equipment should be qualified and computer systems should be validated to demonstrate suitability for the intended use. Electronic records must comply with FDA Part 11 and EU/PICS GMP Annex 11 requirements to ensure data integrity, security and availability. Recent EU and FDA inspection documents prove that qualification, validation and electronic laboratory records are on target of inspectors. The large number of warning letters issued to laboratories also demonstrate that the industry struggles with either understanding or implementing the regulations.

This 2-day course provides the regulatory background and guides attendees through the complete equipment qualification, calibration and computer system validation processes from planning to reporting.

Seminar Pricing Includes (With Stay)

- 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: Requirements and approaches for Instrument Qualification and Computer System Validation

- FDA/EU, ICH and PIC/S requirements
- Lessons from recent FDA Warning Letters and how to avoid them
- Understanding the terminology: qualification, calibration, verification, validation.
- EU/PUCS GMP Annex 15: Validation and Qualification
- USP Chapter <1058> for analytical instruments: current and proposed changes
- Lessons from GAMP®5 and from the GAMP® guide: "A Risk based Approach to Laboratory Systems"
- Planning for cost-effective qualification and validation
- Which instruments require qualification/validation

Lecture 2: Introduction to FDA 21 CFR Part 11 and EU/PICS Annex 11

- Objective, scope, current situation and future of Part11
- Requirements overview and spirit of the regulation
- Requirements for electronic records
- Requirements for electronic and digital signature
- Additional requirements from the PICS/EU Annex 11, from the UK MHRA and from the WHO GMP data integrity guidelines
- FDA/EU inspection and enforcement practices of electronic records: examples of recent FDA warning letters
- User requirements for Part11/Annex 11 based on risk
- Upgrading old or purchasing new systems: compliance and business aspects
- Six steps for implementation of Part11/Annex 11

Lecture 3: Going through the equipment qualification phases

- Develop a project plan from the master plan
- Writing requirement specifications
- Documenting installation and installation qualification
- Testing for initial operational qualification
- Preparing and executing test protocols
- Maintenance, requalification and change control

Lecture 4: Cost Effective Validation of Computer Systems: Step-by-Step - Part 1

- Selecting the right validation lifecycle model
- Going through examples of a complete computer system validation from beginning to end
- How risk assessments can help to determine the type an extent of validation
- Defining user requirements based on risk
- Vendor assessment and supplier agreements
- Going through examples for OQ and PQ testing
- Writing the validation report

Day Two

Lecture 1: Validation of Computer Systems - Part II

- Leveraging validation efforts of identical systems
- Validation of existing equipment and computer systems
- Preparing inspection ready validation documentation
- Integrating the GAMP® guide with USP <1058> for integrated instrument and system validation
- IT infrastructure qualification and validation of networked systems
- Validation and use of cloud computing in FDA/EU regulated environments
- Recommendations for different cloud models and services

Lecture 2: Validation and control of Excel spreadsheet applications

- Designing spreadsheets for compliance
- Validation approach for spreadsheet applications
- When, what and how much to test?
- Recommendations from GAMP®5 for testing native Excel functions
- How to ensure spreadsheet and data integrity
- Going through examples
- Excel spreadsheet validation from beginning to the end: A case study that can be used by everybody

Lecture 3: Maintaining the validated state of computer systems or Control of Operation and Retirement

- Ongoing training of users and IT staff
- System maintenance and data backup
- Change control: Handling planned and unplanned changes
- How to deal with security patches
- Periodic review vs. revalidation
- Disaster recovery and business continuity planning
- Retirement of computer systems and data migration

Lecture 4: Ensuring and documenting Integrity of Laboratory (Raw)data and other Records

- Learnings from the new FDA guide: Data Integrity and GMP Compliance
- Definition of raw data and meta data: FDA/EMA requirements
- What to archive for hybrid systems: paper records or electronic records
- The importance of electronic audit trail to document data integrity
- Review of electronic audit trail: who, what, and how
- How to ensure availability of electronic records throughout the entire retention period
- Steps for validating security and integrity functions
- Examples how to ensure and document data integrity and security
- Preparing your company for data integrity audits

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
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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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