

2-day In-person Seminar:

# Validation and Part 11 Compliance of Computer Systems and Data



Mumbai



April 28th & 29th, 2016



Time: 9 AM to 6 PM

Course "**Validation and Part 11 Compliance of Computer Systems and Data**" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.



## Dr. Ludwig Huber

### Chief Advisor - Global FDA compliance, Agilent Technologies

- 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](http://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. It also helps to fully understand not only the text but also the meaning of Part 11 and Annex 11 requirements to ensure and document integrity and other requirements for electronic records and signatures.

**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
- Understanding the terminology: qualification, calibration, verification, validation.
- EU/PICS 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 systems require qualification/validation

**Lecture 2: 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
- System Suitability testing for performance qualification
- Preparing and executing test protocols
- Preparing inspection ready documentation
- Maintenance, requalification and change control

**Lecture 3: 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
- Risk assessment for type and extent of validation
- Defining user requirements based on risk
- Vendor assessment and supplier agreements
- Testing and documenting installation
- Going through examples for OQ and PQ testing
- Writing the validation report

**Lecture 4: 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
- Validation of mobile apps

**Day Two****Lecture 1: 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 2: Maintaining the validated state of computer systems**

- Ongoing training of users and IT staff
- System maintenance and data backup
- Change control: Handling planned and unplanned changes, e.g., handling security patches
- Periodic review vs. revalidation
- Disaster recovery and business continuity
- Retirement of computer systems and data migration

**Lecture 3: 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 4: Ensuring and documenting Integrity of Laboratory (Raw)data and other Records**

- Definition of raw 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

## Pricing List

Price for One Delegate pass Price: **16,000**

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## Group Participations

Discount Slab: 5 or more participants **10%** discount

To avail the above group discounts, all the participants should register by making a single payment.

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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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