Compliance Online
The Largest GRC Advisory Network

2-day In-person Seminar:

Analytical Instrument Qualification and System Validation

By: **Dr. Ludwig Huber**, Chief Advisor - Global FDA Compliance, Labcompliance

Location: September 14-15, 2017 | Boston, MA




SPEAKER

Dr. Ludwig Huber, Director and Chief Editor, LabCompliance

Dr. Ludwig Huber is Director and Chief Editor of www.labcompliance.com, the global on-line resource for validation and compliance issues for laboratories . Mr. Huber is an expert for FDA and equivalent international compliance and for ISO/IEC 17025 laboratory accreditation. He is also the Chairman, presenter and panel discussion member at US-FDA industry training sessions and conferences.

He served as a 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 equipment. In addition, he was awarded as Presenter of the Year of the Institute for Validation and Technology. He is the author of the books "Validation and Qualification in Analytical Laboratories, and "Validation of Computerized Analytical and Networked Systems", Interpharm Press.

For more information, visit www.ludwig-huber.com

LEARNING OBJECTIVES

Attendees will:

- Learn about the regulatory background and requirements for equipment qualification according to USP <1058> and computer system validation according to GAMP Guides
- Be able to explain the difference between equipment calibration, qualification and system validation
- Learn which equipment/systems need to be qualified or validated
- Be able to allocate equipment and systems to USP <1058> and GAMP categories and to design and execute qualification/validation protocols accordingly
- Understand the logic and principles of instrument qualification and system validation from planning to reporting
- Be able to explain your company's qualification and validation strategies
- Understand how to archive raw data from hybrid systems: electronic vs. paper
- Be able to define and demonstrate Part 11 compliance functionality to auditors and inspectors
- Be able to develop inspection ready documentation during on-going routine operation
- Learn how to ensure, document and audit integrity of raw data and other records

COURSE DESCRIPTION

Analytical 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 are records are on target of inspectors. The large number of warning letters issued to laboratories also demonstrate that they struggle 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 Part 11 and Annex 11 requirements to ensure and document integrity and other requirements for electronic records and signatures.

The course not only ensures a full understanding of the regulations and guidelines for equipment and records but also provides templates and examples to develop inspection ready documentation. Interactive exercises will be dispersed into and between the presentations. About 50% of the total time will be dedicated to practical sessions. Here attendees work in small groups on case studies and prepare the answers using prepared fill-in templates. After the course a large variety of tools such as SOPs, validation examples and checklists will be readily available on a dedicated website that can be used to easily implement what they have learned in the course.

AGENDA Day One: 8.30AM – 05.00PM

08.30 AM - 09.00 AM: Registration

09.00 AM: Session Start

- **09.00 - 09.45: Requirements and approaches for Analytical Instrument Qualification**
  - FDA/EU, PIC/S requirements
  - Qualification/calibration issues in FDA inspections
  - USP Chapter <1058>: current and proposed changes
  - The instrument qualification lifecycle
  - Planning for cost-effective calibration/qualification
- **09.45 - 10.30 (*): Going through the qualification phases**
  - Writing requirement specifications
  - Installation and installation qualification
  - Testing for initial operational qualification
  - Leveraging system suitability testing for on-going performance qualification
  - Preparing inspection ready documentation
- **10:30 - 11:00: Break**
- **11.00 - 11.45 (*): Testing and deviation handling**
  - Developing generic test protocols
  - Documenting test evidence
  - Going through an example test protocol
  - Review and approval of test results
  - Handling deviations
- **11.45 - 12.30: Retrospective qualification and Requalification**
  - Qualification of existing systems
  - Leveraging past experience
  - Time based requalification
  - Event based requalification
  - What and how much to test
- **12:30 - 13:30: Lunch**
- **13.30 - 14.15 (*): Equipment Maintenance and Change control**
  - Preventive maintenance; tasks, documentation
  - Planned and unplanned changes
  - Changing hardware, firmware, documentation
  - Definition and handling of like-for-like changes.
  - Handling changes made by vendors
- **14.15 - 15.00 (*): Type and extend of qualification for USP Instrument Categories**
  - The approach and benefits of instrument categories
  - How to identify the correct category: A, B, C
  - Type and extent of qualification for each category
  - Required procedures and qualification deliverables
  - Responsibilities for instrument qualification
- **15:00 - 15:30: Break**
- **15.30 - 16.15 (*): Requirements and approaches for Laboratory Computer Systems**
  - FDA Part 211, Part 11, PIC/S Annex 11
  - Most critical inspection findings
  - Which systems need to be validated
  - Learning from the new GAMP® guide: “A Risk based Approach to Laboratory Computerized Systems”
  - Examples for risk assessment of computer systems
- **16.15 - 17.00 (*): Validation of Laboratory Computer systems**
  - Writing a validation project plan
  - Going through a complete laboratory computer system validation from beginning to end
  - Integrating the GAMP® guide with USP <1058> for integrated instrument and system validation
  - Writing a validation report as a mirror to the plan
  - Preparing inspection ready validation documentation

Day Two: 8.30AM – 04.30PM

- **08.30 - 09.00: Review of day**
  - Questions and answers from Day 1
  - Main conclusions and action items
- **09.00 - 10.00 (*): Validation and Use of Excel in the QC Laboratory**
  - 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
- **10:00 - 10:30: Break**
- **10.30 - 11.15 (*): Configuration management and Change control**
  - The IEEE model for configuration management and change control
  - The change control process for planned and unplanned changes
  - Versioning of software and computer systems
  - What to test after changes
  - How to document changes
- **11.15 - 12.00 (*): Periodic review and revalidation of chromatographic data system**
  - The approach and practice of periodic review
  - Using periodic review to reduce frequency of revalidation
  - Criteria for time based revalidation
  - Incident requiring revalidation
  - Validation tasks after installing security and other patches
- **12:00 - 13:00: Lunch**
- **13.00 - 13.45 (*): Handling raw data and other laboratory records**
  - Definition of raw data: electronic vs. paper
  - Acquisition and recording of raw data
  - How to make accurate and complete copies of raw data
  - Changing of data and other records
  - Archiving of raw data and ready retrieval
- **13.45 - 14.30: Ensuring Integrity and Security of Laboratory (Raw) data**
  - Most frequent security and integrity issues: going through recent 483's, EIRs and warning letters
  - The importance of electronic audit trail to document data integrity
  - Review of electronic audit trail: who, what, when and how
  - Examples how to ensure and document data integrity
- **14:30 - 15:00: Break**
- **15:00 - 16.15 (*): Auditing Laboratory Computer Systems and records for FDA Compliance**
  - Using FDA Inspections as model for laboratory audits
  - Going through a typical FDA computer system inspection
  - Preparing inspection ready documentation
  - Responding to typical inspectional/audit deviations
  - Learn how to avoid or respond to FDA 483s and warning letters
- **16.15 - 16.30: Wrap up – Final questions and answers**

Note: Sessions indicated with (*) include one or more workshop exercises.
®GAMP is a registered trademark and stands for Good Automated Manufacturing Practice

WHO WILL BENEFIT

- IT/IS managers and system administrators
- QA managers and personnel
- Laboratory managers and supervisors
- Analysts
- Validation specialists
- Software developers
- Regulatory affairs
- Training departments
- Documentation departments
- Consultants

Companies and departments

- Pharmaceutical development and Quality control laboratories
- Quality control laboratories of API manufacturers
- Contract laboratories

2-day In-person Seminar:
ANALYTICAL INSTRUMENT QUALIFICATION AND SYSTEM VALIDATION

Click Here for Venue and Fee Information

Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please contact our offices at (201) 871-0474.

Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $300 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($300) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Seminar Topic: Analytical Instrument Qualification and System Validation

Date & Location: Sept 14-15, 2017. Cambridge MA..

Attendee Details:

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization .....

.....

Address .....

.....

City .....

State ..... Zip.....

Country .....

Phone ..... Fax .....

Payment Options

☐ Check enclosed, payable in U.S. funds to ComplianceOnline (MetricStream, Inc.)

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....

Total amount $ .....

Signature .....
(Signature required on credit card and bill-me orders.)

Print name.....

☐ Bill me/my company $ .....

Purchase order # .....
(Payment is required by the date of the conference.)