Validation and Part 11/Annex 11 Compliance of Computer Systems

by

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Why to attend

Computer systems should be validated to demonstrate suitability for the intended use and to ensure highest system uptime. Validated computer systems used in development, manufacturing and quality control of drugs, drug substances and medical devices is a prerequisite for marketing of related products. Similarly regulatory agencies require records generated by computers to comply with regulations such as the FDA 21 CFR Part 11 and EU Annex 11 to ensure integrity, availability and accuracy of records. While computer system validation in principle is nothing new and regulations for electronic records have been in place since more than 15 years regulatory interpretations and inspections and enforcement practices have changed. Therefore companies are still unsure what and how much to validate and how exactly demonstrate data integrity. Attendees of this seminar will not only learn about current and future requirements and industry practices but will also get specific recommendations and tools for most cost-effective implementation.

The concept

- 50 % of the time will be dedicated to workshop type exercises using prepared fill-in templates and to interactive discussions

In the workshop attendees will practice

- Which computer systems should be validated
- Assessing the risk categories for computer systems
- Writing User Requirement specifications
- Defining vendor requirements
- What to test for operational qualification
- What to revalidate after changes
- Which documentation should be developed when
- Defining Part 11and Annex 11 controls for computer systems

Who will benefit

- Directors
- IT/IS managers and system administrators
- QA managers and personnel
- QC and Lab managers
- Validation specialists
- Software developers
- Regulatory affairs
- Training departments
- Documentation department
- Consultants

Target Companies

- Pharmaceutical development and manufacturing
- Active pharmaceutical Ingredients Industry
- IT/IS Service providers
- Contract laboratories
- Medical device companies
- CROs
- CMOs

Reference material for easy implementation (e-books), all authored by Dr. Huber

- Computer System Validation Master plan (56 pages with templates)
- Primer: Computer System Validation (46 pages)
- Computer System Validation: Step-by-step implementation (10 pages)
- Computer system validation: Step-by-step – Best practice guide
- 21 CFR Part 11: Step-by-step - Best practice guide
- Checklists for Part 11 and Annex 11
- Five SOPs for computer validation and Part/Annex 11
- Examples for computer validation from planning to reporting

Day 1

Module 1: Regulatory requirements and recommendations from Industry Task Forces

- Why to validate computer systems
- FDA and EU requirements for software and computer system validation
- FDA Inspection and Enforcement Practice
- How does validation help to improve your business
- Examples of recent Warning Letters and 483s
- Which systems need to be validated
- Computer validation according to GAMP®5
- Selecting the right validation approach for commercial off-the-shelf system
- Using the risk based validation approach to lower costs
- Step-by-step instruction for risk assessment according to most recent guidelines
- Workshop exercises

Module 2: Eight Steps for Cost Effective Computer System Validation

- Forming the validation team: Selecting the right members and a project leader
- Planning for effective implementation
- Writing meaningful specifications
- Selecting and qualifying the right vendor using the risk based approach
- Preparing the site for installation
- Installing and testing the system for correct operation
- Testing during on-going use: what and how
- Validating existing systems
- Change control and revalidation
- Workshop exercises

Module 3.Initial and ongoing tests of software and computer systems

- How to reduce costs though risk based testing using the traceability matrix
- Justify and document what and how much to test
- Leveraging vendor testing
- Understanding FDA warning letter phrases: testing for worst cases, high load, limit
- Testing COTS systems according to GAMP®55
- Developing a test plan and protocols
- Required training documents of IT professionals and test engineers: don’t forget GMP training
- How to conducting and document tests: demonstrating test evidence
- Review and approval of test protocols
- Handling deviations
- Workshop exercises

Module 4: Minimum Validation Documentation Inspectors want to see

- Why are the validation plan and validation report the most important documents
- Supplier agreement
- Supplier assessment reports
- Change control procedures and change control logs
- Back-up and archiving strategy
- Evaluation and review of computer systems
- Internal audit records versus reviews
- Contingency Plan
- Disaster recovery plan
- Reduce validation costs by using easy to understand and use fill-in blank validation documents
- Going through examples and fill-in templates

Day 2

Module 5: Validation and Use of Excel Spreadsheets in regulated environments

- Regulatory requirements for spreadsheets; FDA Part 11, PIC/S Good Practice Guide. and the EU Annex 11
- Recommendations from the new GAMP®5
- How does FDA use Excel to comply with its own regulations: going through two FDA information bulletins
- How to design spreadsheets for compliance.
- The reduced lifecycle for cost effective validation
- How to ensure and validate spreadsheet integrity.
- When, what and how much to test?
- Validation of standard/native Excel functions?
- Specifics of Excel spreadsheets and Macro programs
- Excel spreadsheet validation from beginning to the end: A case study that can be used by everybody
- Workshop exercises

Module 6: Qualification of Network Infrastructure and Validation of Networked Systems

- Why to qualify infrastructure if we validate the system anyway
- Recommendations from FDA and GAMP®5
- Configuration management and change control as the most important network qualification steps
- Qualification of PC clients, servers, data centers
- What and how much to test with the risk based cost/benefits in mind:
- Qualification of network components, servers, PC clients,
- Documentation requirements: SOP, installation and test scripts, system diagrams, change logs

- What to do with new security patches
- Going through a real life inspection
- Qualification of virtual networks and cloud computing
- Using the internet and cloud computing in regulated environment
- Workshop exercises

Module 7: Understanding the spirit and basics of the FDA Part 11 and the EU GMP Annex 11

- FDA and EU requirements for electronic records and signatures: similarity and differences
- FDA inspection and enforcement practices of electronic records: examples of recent FDA warning letters
- History, current status and future of Part 11 and Annex 11
- The difference between electronic and digital signatures
- E-signature requirements for Annex 11 and Part 11
- Deciding which systems require Part 11/Annex 11
- Define user requirements for Part11/Annex 11 based on risk
- Performing a Part 11 gap analysis
- Upgrading old or purchasing new systems: compliance and business aspects
- Six steps for risk based implementation of Part 11/Annex 11

Module 8. Learn how to ensure and document data integrity for Part 11/EU Annex 11 Compliance

- What to archive for hybrid systems: paper records or electronic records
- Justification and documentation your approach towards Part 11/Annex 11 documentation
- Raw data: Definition, acquisition, maintenance and archiving
- Defending data security and integrity
- Audit trail: the most important function to demonstrate data integrity
- FDA expects to review audit trails: who, what, how many times
- When do we must keep e-records after print out: 5 eye opening case studies
- Auditing computer systems for Part 11/Annex 11 compliance
- 'Must' documents you must have for FDA/EMA Part 11/Annex 11 inspections
- Going through model case studies
- Workshop exercises
- Final discussion and wrap-up

ABOUT THE COURSE DIRECTOR

Dr. Ludwig Huber – Past and present

- Chairman, presenter and panel discussion member at seminars and presentations for the US FDA, ISPE, PDA, PIC/S and several national health agencies
- Published more than 100 papers and 4 text books on different aspects of validation FDA/EU complaince
- Team and 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.
- 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.
- Member of the advisory board of the European Compliance Academy

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

PROGRAM AGENDA

05 & 06 June 2013

08.30am	Registration&Continental Breakfast
09.00am	Course begins
10:30am	Mid-morning Refreshment Break
11:00am	Course Continue
12:30pm	Luncheon
13.30pm	Course Continue
15:15pm	Mid-Afternoon Refreshment Break
15:30pm	Course Continue
17:00pm	Questions&Answers
17:30pm	End of the day

COURSE LOCATION & HOTEL ACCOMMODATIONS

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COURSE REGISTRATION FEE

One person from 780.00 Euro/person (+18% VAT)
Two people from 750.00 Euro/person (+18% VAT)
Three or more people from 700.00 Euro/person (+18% VAT)

COURSE REGISTRATION

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