



Computer System Validation and 21 CFR Part 11 Compliance for (Bio) Pharmaceutical and Device Industry

January 20-21, 2009 • Embassy Suite Hotel • Isla Verde, P.R

Outline

This seminar is designed for attendees looking to gain a comprehensive understanding of [computer system validation](#) and to comply with [Part 11 of the FDA's 21 CFR](#). Fifty (50) percent of the seminar is dedicated to case studies and examples.

This interactive course will provide understanding of the regulatory requirements for software and computer system validation and of the implementation of validation for commercial software and computer systems. It will also provide guidance on how to define specific system Part 11 requirements based on risk and predicate rule requirements, while showing the tools to implement this in your organization.

Who should attend

- Everybody dealing with electronic records used in FDA and other regulated industries
- IT/IS Managers and administrators
- QA managers and personnel
- Quality control managers and staff
- Analysts and lab managers
- Validation specialists
- Software developers
- Members of change control boards
- Regulatory affairs
- Human resources (HR) managers and staff
- Training departments
- Documentation department
- Consultants

Duration

Two days.

About the Instructor

Dr. Ludwig Huber has been responsible for the cGMP compliance program at Agilent and HP for 15 years. He has published more than 100 papers on validation, compliance and 21 CFR Part 11. He is the author of several books, such as “[Validation and Qualification in Analytical Laboratories](#)” and “[Validation of Computerized Analytical and Networked Systems](#)”.

He is also the author and editor of www.labcompliance.com, an on-line resource for validation and compliance issues in laboratories. Dr. Huber has been a member of the PDA Task Force on 21 CFR Part 11 and of the GAMP Special Interest Group on Laboratory Equipment. Currently, he is on the advisory board of the European Compliance Academy and was a member of the IVT task force on network qualification.

Learning Objectives

At the completion of this course, participants will be able to:

- Understand regulatory requirements for software and computer system validation
- Understand the process throughout the entire validation lifecycle from planning to retirement
- Learn how to effectively implement validation of commercial software and computer systems
- Learn how to validate configurable and customized software and systems, e.g., MS Excel
- Learn how to document software and computer system for FDA and equivalent international agencies
- Understand the spirit and current and future requirements of FDA's 21 CFR Part 11
- Learn about FDA's inspection and enforcement practices for electronic records
- Learn how to define system specific Part 11 requirements based on risk and predicate rule requirements
- Learn how to perform a gap analysis between Part 11 requirements and existing systems and procedures
- Learn how to effectively implement Part 11 in your organization
- Learn how to justify and document your approach for Part 11

REGISTER NOW!

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Course Schedule

First Course Day: January 20, 2009

FDA and International Requirements and Enforcement

- FDA regulations: CFR Parts 211, 58, 820, and Part 11
- FDA computer system validation guidance documents
- Examples of FDA 483's and Warning Letters
- International regulations and guidelines: EU GMPs, new Annex 11, PIC/S
- Industry guides: GAMP® 5, PDA, IEEE

Validation lifecycle from planning to retirement (I)

- System development lifecycle: V-model, 4-Q model
- Developing a validation master plan
- Developing a validation project plan
- Developing requirement specifications
- Validation at the vendor and vendor assessment
- Installation and configuration (IQ)
- Testing for operation (OQ), what, how much, how to document
- Ensuring on-going performance

Validation lifecycle from planning to retirement (II)

- Ensuring initial and on-going system performance (PQ)
- Validation of existing systems
- Review and revalidation: event and time based
- The validation summary report
- Responsibilities for validation
- Key procedures and templates

Functional testing (how much is enough?)

- What to test
- Link to user requirements (traceability matrix)
- Developing test protocols
- Leveraging tests between systems
- Using and validating automated test tools
- Documenting tests

Auditing Computer Systems

- Developing an SOP for audits of computer systems.
- Assigning responsibilities
- Conducting the audit: : review procedures, walk through the computer system area
- Most critical questions to ask
- Documenting detailed audit findings
- The audit summary report
- Effective follow up
- Presenting evidence of the audit to the FDA
- Learning's for FDA inspections

Configuration Management and Change Control

- Defining configuration management vs. change control
- Reviewing a change control procedure
- Change control for hardware, operating systems and application software
- The change control process for planned and unplanned changes
- Versioning of software and computer systems
- What to test after changes
- How to document changes

Risk based validation of software and computer systems

- Guidance from regulatory and industry task forces: ISO, ICH, GHTE, NIST, GAMP/ISPE
- Practical approach for risk assessments
- How to develop a risk based software and computer validation program
- Validation tasks for risk categories for each life cycle phase, from planning to routine use
- Validation tasks segmented by system complexity

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Course Schedule

Second Course Day: January 21, 2009

Network Infrastructure Qualification

- The GAMP/ISPE Good Practices Guide and IVT standard
- Principles of network infrastructure qualification
- Compliance concepts for infrastructure vs.
- Qualification of PC clients, servers, data centers
- How to ensure highest system uptime with on-line monitoring
- Documentation requirements
- Going through a life inspection
- Software tools for infrastructure qualification

Validating and Use of Excel Applications

- Typical compliance problems with spreadsheets
- How to design spreadsheets for compliance.
- How to ensure and validate spreadsheet integrity
- Validation of standard Excel functions?
- Validation of 'ad hoc' spreadsheet applications.
- How to document planning, specifications, installation, testing and changes.

Putting it all together for different applications

- Laboratory systems (LIMS, Electronic lab note books, chromatography systems)
- Electronic document management systems
- Clinical data acquisition systems
- Manufacturing systems (MES, EBR, PLC, SCADA, ERP, DCS)
- Medical devices

Overview of 21 CFR Part 11

- The original intent of Part 11
- Part 11 history, current status and future

- Other regulations: SOX and HIPAA
- FDA's inspection and enforcement practices: Early and recent FDA 483's and Warning Letters
- International regulations and guidelines: EU GMPs, Annex 11, PIC/S
- Recommendations from the industry, e.g., GAMP

Part 11 Requirements

- Validation
- Limited and authorized access
- Accurate and complete copies
- Archiving and ready retrieval
- Electronic audit trail
- Electronic signatures for closed systems
- Digital signatures for open systems
- Authority and device checks

FDA's New Approach: Now and in the Future

- FDA's New Guidance on scope and applications
- FDA's guidance on using computers in clinical trials
- Recent FDA presentations and personal discussions
- FDA's upcoming concern on data integrity
- Focus on predicate rules and risk assessment
- Changes for the 'New' Part 11
- Implementing the 'New' Part 11
- Case Studies



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Registration Form

1. Please type or print your name, address and affiliation.

Mr. Ms. Dr. First Name Middle Initial Last Name

Job Title Company

Business Address

City State/Province Zip Code Country

Phone Fax E-mail

2. Course & Fees: REGISTER TODAY and take advantage of the group discounts by having your entire team attend: SEND YOUR WHOLE TEAM! Send three or more individuals from the same company and receive **15%** off in all registration (Registrations must be received together).

- Early Registration Fee \$1,905 (Due Date: November 5, 2008)
 Regular Registration Fee: \$2,095

3. Please check the appropriate box

Check Enclosed Charge to: Master Card Visa AMEX

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Signature _____ Date _____

4. Return complete form with payment (Payment must be included to be considered registered) made to:

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Professional education interest: (Check all that apply):

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| <input type="checkbox"/> Validation | <input type="checkbox"/> Sterilization | <input type="checkbox"/> Parenterals | <input type="checkbox"/> Engineering | <input type="checkbox"/> Statistics |
| <input type="checkbox"/> Maintenance | <input type="checkbox"/> Microbiology | <input type="checkbox"/> Utilities | <input type="checkbox"/> Aseptic Processing | <input type="checkbox"/> Cleaning Validation |
| <input type="checkbox"/> Computer Validation | <input type="checkbox"/> Biotechnology | <input type="checkbox"/> HVAC | <input type="checkbox"/> Env. Monitoring | <input type="checkbox"/> Process Validation |

Confirmation: Written confirmation will be sent to you once payment is received. **Substitutions:** If a registrant is unable to attend, substitutions are welcome and can be made any time. If you are pre registering as a substitute attendee, indicate in the registration form. Should you be unable to attend, please inform us in writing prior to 10 days and a credit voucher will be awarded which is applicable to a training course one year from date of issue. **Event Cancellation:** ECHO reserves the right to modify the material or instructor without notice or to cancel the event. If the event must be cancelled, registrant will be notified as soon as possible and will receive a full refund of fees paid. ECHO cannot be responsible for airfare penalties or other cost incurred due to a cancellation. Course enrollment is limited for the benefits of all attendees; this necessitates early registration.