Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Data Integrity: FDA/EU Requirements and Implementation

Zurich, Switzerland

September 27th & 28th, 2017

9:00 AM to 6:00 PM

Price

Price: **$1,695.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$5,085.00** You Save: $3,390.0 (40%)*

~~$8,475.00~~

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.
- Author of the books "Validation and Qualification in Analytical Laboratories, and "Validation of Computerized Analytical and Networked Systems"

Overview :

There is no doubt that data integrity is the current and future inspection focus of all regulatory health care agencies. More than 50% inspection reports such as 483's and Warning Letters quote data integrity as deviations from GxP regulations.

This new 2-day course provides the regulatory background and guides attendees through the complete record lifecycle from data entry or acquisition through evaluation, reporting, archiving and retrieval. It also helps to fully understand not only the text but also the meaning of related regulations such as FDA's Part 11 and the EU/PICS Annex 11.

Agenda:

Day One

Lectures and Workshop Exercises

Lecture 1: Definitions, requirements and approaches for data integrity

- Definition of data integrity: ALCOA+
- The importance of data integrity for public health
- Main reasons for non-compliance
- Regulations and guidelines
- FDA's inspection and enforcement strategy of Part 11
- Lessons from recent FDA Warning Letters and how to avoid them

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

- Objective, scope, current situation and future of Part11
- Requirements for electronic records
- Requirements for electronic and digital signatures
- Additional requirements from the PICS/EU Annex 11,
- Developing a gap analysis
- Upgrading existing or purchasing new systems:
- Six steps for implementation of Part11/Annex 11

Lecture 3: Strategies to detect and avoid integrity issues

- Recruit, train and retain employees who will be responsible for ensuring data integrity
- Preventing data integrity issues: Going through details of ALCOA+
- Possible causes for data integrity breaches
- Understand system vulnerabilities, motivation and likelihood operators might compromise data
- Understand the company's quality culture
- Understand high risks in the data lifecycle
- Learning from internal audits and FDA inspections

Lecture 4: The Quality System as Prerequisite for Data Integrity

- Contributing factors to poor quality
- Consequences of poor quality systems
- Recommendations from the FDA
- Developing a Quality Culture
- ICH Q10 - The quality system for pharma industry
- Implementing key requirements: e.g., CAPA system, failure investigations, training, audits
- Assessment of data integrity risks
- Steps for on-going improvement

Day Two

Lectures and Workshop Exercises

Lecture 5: Cost effective Validation of software and computer systems

- 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 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
- Maintaining the validated state

Lecture 6: Definition and Handling of Raw Data

- Definition of Raw Data
- Examples of raw data
- Raw data for paper based and electronic systems
- Criteria for electronic raw data with paper print-outs
- Raw data management along the data lifecycle
- Changing of raw data
- Archiving of raw data from electronic and hybrid systems
- Going through examples

Lecture 7: Good documentation practices to ensure data integrity

- Requirements for documentation (ALCOA+)
- Documents that must be readily available
- Examples for good and bad documentation
- Good practices for paper and electronic data
- How to avoid common documentation mistakes
- The importance of global documentation
- Examples

Lecture 8: Data Integrity Auditing: Internal and FDA inspections

- Going through a typical FDA inspection as a model for internal audit
- FDA's new approaches to data integrity inspections
- Typical audit questions
- Identifying systems that must be audited based on risk
- Typical audit findings
- The importance of the exit meeting
- Writing a corrective and preventive action plan to fix data integrity audit findings

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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

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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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