Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Validation, Verification and Transfer of Analytical Methods (Understanding and implementing guidelines from FDA/EMA, USP and ICH)

Zurich, Switzerland

June 7th & 8th, 2017

9:00 AM to 6:00 PM

Price

Price: **$1,895.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$5,685.00** You Save: $3,790.0 (40%)*

~~$9,475.00~~

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 :

Analytical methods and procedures should be validated to ensure reliability, consistency and accuracy of analytical data. Compendial methods should be verified to demonstrate the suitability of laboratories to successfully run the method and when methods are transferred between laboratories successful transfer should be demonstrated through testing. In case a laboratory wants to use an alternative method instead of a compendial method, equivalency of the alternative method to the compendial method should be demonstrated.

Agenda:

Day One

Lectures and Workshop Exercises

Lecture 1: Regulatory Background and Requirements

- FDA and international requirements
- The importance of ICH Q2 and USP chapters
- USP approach for method validation: New/revised Chapters 220, 1200, 1210, 1220, 1225
- Learnings from the NEW FDA and WHO method validation guidelines
- Different requirements for GLP, GCP and GMP
- The importance and steps of risk assessment
- Exercise: Define risk numbers for different methods
- Lessons from recent FDA Warning Letters
- Planning for cost-effective implementation

Lecture 2: Preparing Your Lab for Validation Studies

- Analytical Instrument qualification
- Part 11/Annex 11 compliance of computer systems
- Validation of chromatographic data systems
- Validation and control of Excel spreadsheets
- Qualification of reference standards and materials

Lecture 3: Validation of Analytical Methods and Procedures

- Developing a validation plan and SOP
- ICH Q2 validation and test parameters:

  Accuracy, precision, intermediate precision, specificity, LOD, LOQ, linearity, range, robustness, ruggedness
- Examples for application specific acceptance criteria
- Examples for design and execution of test experiments
- Evaluation of test results: using statistical models
- Handling deviations from expected test results
- Going through an example validation report

Lecture 4: Verification of Compendial Methods

- FDA and equivalent international expectations
- Scope and objectives of USP <1226>
- USP <1226> verification requirements
- Risk based approach for type and extent of verification testing
- Which validation parameters should be verified
- Logical process to set acceptance criteria
- Exercise: Application based verification testing

Day Two

Lectures and Workshop Exercises

Lecture 1: Transfer of Analytical Methods and Procedures

- The main objective of formal method transfer
- Learnings from EU GMP Chapter 6 on method transfer
- USP <1224> : Choosing the approach for transfer
- Approach and benefits of comparative testing:
- Developing a risk based test plan
- Planning and developing an effective transfer protocol
- Preparing the receiving lab for the transfer
- Method transfer to new technology:: HPLC to UHPLC
- Preparing the method transfer report
- Exercise: Application specific comparative testing

Lecture 2: Demonstrating Equivalency to Compendial Methods

- Method validation vs. equivalency testing
- Definition, objective and scope of alternative methods
- Justification for the use of alternative methods
- FDA and USP requirements
- Options for alternatives to approved procedures
- Exercise: Equivalency testing - what and how much
- Documentation requirements

Lecture 3: Maintaining the Validated State

- Monitoring method performance: system suitability testing and quality control samples
- Change control procedure for analytical methods
- Handling method changes vs. adjustments
- Revalidation of analytical methods: when, what to test
- Method reviews as a cost effective alternative to time based revalidation
- Going through a review process
- Regulatory reporting of post-approval changes
- Examples for continuous improvements

Lecture 4: Special Applications and Validation Processes

- Preview to the expected new USP general chapter <1220> "The Analytical Procedure Lifecycle"
- Method development and validation using Quality by Design principles following the new FDA Guidance
- Validation of bioanalytical methods according to the FDA and EMA guidelines
- Validation of stability indication method

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

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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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