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2-Day Workshop by Dr. Huber:

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

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

Location: September 12-13, 2017 | Boston, MA

SPEAKER

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

Dr. Ludwig Huber, Ph.D., is the chief advisor and editor of www.labcompliance.com, the global online resource for validation and compliance. He is the author of the books "Validation and Qualification in Analytical Laboratories" and "Validation of Computerized Analytical and Networked Systems, Informa Healthcare." He has given more than 300 presentations mainly on GLP/GMP, 21 CFR Part 11 and Validation around the world. This includes seminars, workshops and presentations for the US FDA, China CFDA, ISPE, PDA, PIC/S and several other industry organizations and national health care agencies.

LEARNING OBJECTIVES

- Learn about the regulatory background and requirements for validation of analytical methods and procedures
- Learn how to plan, execute and document development and validation of methods developed in-house
- Be able to explain the different requirements for validation, verification and transfer of analytical procedures
- Understand the principles of validating methods developed in-house, verification of compendial methods, transfer of analytical procedures and demonstrating equivalency to compendial methods
- Be able to explain your company's strategy for method validation, verification, transfer and equivalency testing
- Be able to select test parameters, test conditions and acceptance criteria for different analytical tasks
- Be able to justify and document decisions about revalidation after method changes
- Be able to define and demonstrate FDA and EU compliance to auditors and inspectors
- Be able to develop inspection ready documentation during on-going routine operation
- Understand statistical evaluation of validation test results
- Understanding what questions will be asked during audits and inspections and how to answer them

Handouts/ Bonus Material for Easy Implementation (available as web downloads):

- 70-page primer: Validation of analytical methods (authored by Dr. Ludwig Huber)
- 10 SOPs related to validation, verification, transfer, review and change of analytical methods
- 10 checklists, templates and examples
- Acceptance criteria for different analytical tasks

COURSE DESCRIPTION

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.

Method validation recently got highest attention from regulatory agencies and industry task forces. For example, FDA and EMA released guidelines on method validation and transfer, and USP has proposed new approaches chapters for integrated validation, verification and transfer of analytical procedures, for equivalency testing and for statistical evaluation.

This 2-day workshop will give attendees the background to understand the requirements, and even more significantly, it will focus on strategies and provide tools to implement most critical requirements. It will also provide templates and examples to develop inspection ready documentation. Interactive workshop exercises will be dispersed into and between the presentations. About 50% of the total time will be dedicated to practical sessions with real life examples. After the course a 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 attendees have learned in the course.

AGENDA

Day One (8:30 AM – 4:30 PM)

8:30 AM - 9:00 AM: Registration Process

9:00 AM: Session Start

Lectures and Workshop Exercises

Lecture 1 - Regulatory Background and Requirements

- FDA and international requirements
- The importance of ICH Q2 and USP chapters
- New USP Chapter 220, 1200, 1210, 1220
- Different requirements for GLP, GCP and GMP
- Impact of pharmaceutical quality systems
- The importance of risk assessment
- Lessons from recent FDA Warning Letters
- Planning for cost-effective implementation

Lecture 2 - Preparing Your Lab for Validation Studies

- Analytical instrument qualification
- Part 11 and Annex 11 compliance of computer systems and software
- Validation of chromatographic data systems
- Validation and control of Excel spreadsheets
- Training of analysts
- Documenting evidence of training efficiency
- 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
- Setting application specific acceptance criteria
- Efficient design and execution of test experiments
- Evaluation of test results: using statistical models
- Handling deviations from expected test results

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 testing
- Which validation parameters should be verified
- Logical process to set acceptance criteria

Day Two (8:30 AM – 4:30 PM)

Lectures and Workshop Exercises

Lecture 5 - 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
- Preparing the receiving lab for the transfer
- Method transfer to new technology: HPLC to UHPLC
- Preparing the method transfer report

Lecture 6 - Demonstrating Equivalency to Compendial Methods

- Definition, objective and scope alternative methods
- Justification for the use of alternative methods
- FDA and USP requirements
- Options for alternatives to official procedures
- Equivalency testing: what and how much
- Documentation requirements

Lecture 7 - 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
- Regulatory reporting of post-approval changes
- Continuous improvement

Lecture 8 - Special Applications and Validation Processes

- Validation for INDA, ANDA and NDA submissions
- Validation of bioanalytical methods according to the FDA and EMA guidelines
- Validation of stability indication methods
- The integrated method lifecycle management: activities during development, validation and routine use
- Method development and validation using QbD

WHO WILL BENEFIT

- QA managers and personnel
- Quality control
- Method development
- Analytical chemists
- Validation specialists
- Laboratory managers and supervisors
- Regulatory affairs
- Training departments
- Documentation departments
- Consultants

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

Date & Location: .....

Attendee Details:

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Attendee 2			
Attendee 3			
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