# CRITICAL COMPLIANCE DISCUSSION

## A Seminar with Compliance Expert Dr. Ludwig Huber

### COMING TO A CITY NEAR YOU!

**Join Dr. Huber**

Ludwig Huber, PhD, is director at Labcompliance and editor of **www.labcompliance.com**, the global online resource for validation and compliance.

**Locations:**

**May 11, 2015**
The Courtyard by Marriott
Boston-Cambridge
777 Memorial Drive
Cambridge, MA 02139

**May 12, 2015**
Hilton Garden Inn Bridgewater
500 Promenade Boulevard
Bridgewater, NJ 08807

**May 13, 2015**
The DoubleTree by Hilton
Raleigh Durham Airport at Research
Triangle Park
4810 Page Creek Lane
Durham, NC 27703

**May 14, 2015**
Regus Schaumburg
10 N. Martingale Road, Suite 400
Schaumburg, IL 60173

**May 15, 2015**
South San Francisco Conference Center
255 South Airport Boulevard
South San Francisco, CA 94080

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Printed in USA, April, 2015
5991-5735ENUS

### Join Industry Experts and Participate in this Important Agenda

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| 8:30 a.m. | Introduction and Welcome |
| 9:00 a.m. | Recent regulatory updates and trends in analytical method validation – Dr. Ludwig Huber |
| 10:00 a.m. | "Quality by Design" based workflow to develop and transfer analytical methods – Andreas Tei |
| 11:00 a.m. | Lessons from pharmaceutical laboratory related FDA Warning Letters – Dr. Ludwig Huber |
| 12:00 noon | Update on Workflows for Leachables and Extractables in the Pharma Industry – David Weil |
| 1:00 p.m. | Lunch and Discussion with Dr. Huber and Speakers |

Please see page 2 for abstracts.

*The seminar will be complemented with a 32-page primer: "Compliance by design for pharmaceutical quality control laboratories" Insight from FDA Warning Letters, published by Agilent Technologies and authored by Ludwig Huber.*

Attendance is complimentary, but you must register today to attend. Space is limited.

Register for your seat NOW **www.agilent.com/chem/Compliance_Tour2015**

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## RECENT REGULATORY UPDATES AND TRENDS IN ANALYTICAL METHOD VALIDATION

Dr. Ludwig Huber

Recently several guidelines have been released from regulatory bodies and industry task forces for method development, validation and transfer. They include new FDA guides for method validation with elements of quality by design and for bioanalytical method validation, a new GMP chapter from Europe for method transfer, a new report from PDA on the lifecycle approach for analytical method validation of biotechnology products and several USP chapters with impact on revalidation and statistical evaluation. This presentation will discuss critical requirements and give recommendations on how to effectively implement them for (bio)pharmaceutical development and QC laboratories.

## LESSONS FROM PHARMACEUTICAL LABORATORY RELATED FDA WARNING LETTERS

Dr. Ludwig Huber

Recent FDA statistics show that laboratory controls are amongst the top warning letter deviations. Furthermore, an analysis of several hundred letters revealed that the letters get more and more detailed, such that in the meantime there are deviation examples for all activities in the analytical lab. Going through the entire sample and data flow from sampling to archiving of records this presentation will provide typical examples of citations with recommendations on how they could have been avoided. This presentation will also demonstrate that studying warning letters can not only be beneficial in getting prepared for the next FDA inspection and other external audits, but that they are ideal to design compliance into the laboratory and to develop a detailed training program.

## "QUALITY BY DESIGN" BASED WORKFLOW TO DEVELOP AND TRANSFER ANALYTICAL METHODS

Andreas Tei

"Quality by Design" (QbD) is a systematic approach eliminating the variability of industrial processes. The aim is to ensure a consistent process quality by compensating for variability to obtain a consistent product quality. The QbD approach will also be applied for the development of analytical methods. In this presentation, we will discuss workflow solutions that support automated method development and method transfer processes under QbD guidelines.

## UPDATE ON WORKFLOWS FOR LEACHABLES AND EXTRACTABLES IN THE PHARMA INDUSTRY

David Weil

One of the most written about topics in the industry today. Gain a fresh perspective on the workflows and analytical solutions required to be in compliance.

## DR. LUDWIG HUBER

Ludwig Huber, PhD, is director at Labcompliance 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". He has given multiple presentations mainly on GLP/GMP, 21 CFR Part 11 and Validation around the world. This included seminars, workshops and presentations for the US FDA, China FDA, and several other national healthcare agencies.

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