# PHARMACEUTICAL & COMPLIANCE SEMINAR TOUR 2013

The pharmaceutical industry faces constant challenges, as business, science, and regulatory pressures evolve and collide. From personalized medicine, to CROs, the process of bringing drugs to market today is dramatically changing. At Agilent Technologies, we have developed a comprehensive portfolio of measurement platforms to help you achieve success in pharmaceutical industry for a long time. From Agilent pharmaceutical compliance summit, you can learn how you can prepare your lab environment to meet recent pharmaceutical compliance guidelines with Dr. Ludwig Huber. Also, you can identify Agilent pharmaceutical compliance-ready solutions using chromatography and lab software technology.

**Date:** 8 April 2013 (Monday)

**Venue:** Agilent Technologies Sdn Bhd
Bayan Lepas Free Industrial Zone, 11900 Penang, Malaysia

To register, please visit [www.agilent.com/chem/PharmaSeminar2013](http://www.agilent.com/chem/PharmaSeminar2013)

## Agenda

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**Because of extreme toxicity even at lowest levels Genotoxic Impurities (GTIs) require special control beyond general ICH impurity guidelines. This presentation will specifically address**

- Specific situation of genotoxic impurities: sources, toxicity, five-class system for categorizing GTIs
- Expectations from EMA, FDA and anticipated ICH M7 Guideline to reduce GTIs to below the acceptable threshold of toxicological concern (TCC)
- Step-by-step recommendations to implement regulatory GTI

| 10:00am | Break                                                                 |                        |
| 10:20am | Agilent solutions for Genotoxic impurity analysis                    | Michael Kraft          |

- LC tools from Agilent: HDR and 2DLC

**This presentation will give you an overview about the requirements for the analysis of genotoxic impurities in API’s and drug products, including the applicability of the latest solutions in UHPLC from Agilent with a brief outline of the 1200 Infinity Series and the Agilent Value Promise: Compatible and Scalable Across and Between Series**

- Introduction to the new Agilent 1200 Series High Dynamic Range (HDR) DAD solution, which offers Up to 30x higher sensitivity for better data quality due to higher area precision
- Introduction to 2DLC, a new level of separation power, detection sensitivity and precision to utilize a single ultra-high peak capacity run instead of many conventional runs – with 1 min method setup!

| 11:10am | Solutions for efficient method development and transfer in pharma QC | Michael Kraft          |

- multi method dev. & ISET2

**This presentation will give you an overview about the requirements for Method Development and Method Transfer with focus on the new chapter USP <1224>, including the applicability of the latest solutions in UHPLC from Agilent**

- Introduction to the Agilent Method Development System, including new valve solutions which offer highest flexibility for any application and workflow need
- The new version of the Intelligent System Emulation Technology (ISET II), which now enables method transfer even between different vendors’ LC

| 12:00pm | Lunch                                                                 |                        |
| 1:00pm  | Introduction of new GC & GC/MS system                                | Lotus Saw              |
1:15pm  Agilent solutions for Genotoxic impurity analysis  
- LC/MS/MS analysis solution for Genotoxic impurity analysis  

SPEAKER: Christopher Bowen

1:45pm  Analysis in Pharmaceuticals, USP 232/233  
with Agilent Atomic Spectroscopic Solutions

New USP chapters <232> and <233> for the measurement of inorganic contaminants in pharmaceutical samples are scheduled to be implemented in early 2014. The requirement for the testing of pharmaceutical samples – Excipients, intermediates and final products – Has been growing in recent years, and will continue to grow. Particularly in the measurement of trace metals, which is driven by the update of USP methods from old wet chemical methods to ICP-OES and ICP-MS. The greater throughput of ICP-OES and ICP-MS demands increased efficiency and productivity in sample preparation. USP <232> defines the analytic limits, while USP <233> defines sample preparation options including closed vessel microwave digestion, and recommends the use of modern instrumentation, such as multi-element ICP and ICP-OES techniques. Analytical equipment qualification under USP <233> is based on performance testing, and includes requirements to demonstrate accuracy, repeatability, and the unequivocal identification of analytes. Here, we present data to illustrate the successful validation of the Agilent Atomic Spectroscopic Solutions according to USP <232>/<233>.

2:15pm  Determination of Class I, II and III Residual Solvents in Pharmaceuticals by USP <467> with Agilent 7897A Headspace Sampler

Residual solvents in pharmaceuticals may remain from the manufacturing process of the active pharmaceutical ingredients or final product. Analysis of residual solvents in pharmaceuticals is extremely important to protect patient safety.

In this presentation, we will discuss the use of Agilent 7897A headspace sampler coupled to a Agilent 7890A GC for the analysis of USP <467> Class 1 and Class 2 residual solvents at their limit concentrations. Headspace control software fully integrated into the chromatography data software was used for method development and final analysis. Additional configurations for dual column confirmation using FID-FID and FID-MSD are described.

2:45pm  Break

3:00pm  Meeting 21 CFR Part 11 with OpenLAB Software Suite

SPEAKER: Caleb Ng

Today’s small to medium-sized chromatography laboratories are faced with demanding information management challenges driven by the complexity of managing multiple chromatography systems, the need for data security, and increasing regulatory requirements. At the same time, it is necessary to achieve increasingly higher levels of productivity. Most available data management solutions have also been designed for large laboratories and do not easily scale down to meet your needs. Agilent has developed OpenLAB Data Store/ECM as a simple, affordable, solution for the centralized storage of OpenLAB CDS data with all the built-in features necessary for achieving regulatory compliance.

3:30pm  Recent column technology in Poroshell 120 and HILIC advantages in Pharma analysis

SPEAKER: Bradley Terence Skelchyi

(ITTech Research)

Recent column technology in Poroshell 120, example of real run analysis of Acarbose. HILIC advantages in Pharma analysis.

4:00pm  Agilent’s Harmonized analytical instrumentation protocol approach to Multi-Vendor compliance

SPEAKER: Dick Fregin

Compliance for the Instrument and the Laboratory  
- ACE – Agilent Compliance Engine  
- Fully automated compliance protocols  
- results fully traceable to raw data  
- reporting free of transcription error  
- automated Pass / Fail report  
- Enterprise Edition provides Universal Protocol with the accuracy of an automated, paperless execution plus:  
- Compatible with all leading Chromatography Suppliers (vendor agnostic)  
- Harmonized protocols – 1 protocol 1 technique  
- Testing flexibility maintains SOP conformance while enabling user required specific parameters  
- Broad Compliance Offering portfolio providing DQ/IQ/OQ/PV services across a range of OEM products

4:30pm  Q&A/Closing

Speakers

“Dr. Ludwig Huber is the director and editor of Labcompliance, 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, SFDA, KFDA, HSA, ISPE, Japan PDA, PIC/S and several national health agencies”. For more information, please visit Dr Huber’s website www.ludwig-huber.com

Michael Kraft is the worldwide Industry Marketing Manager for Agilent’s Liquid Phase Separations Business. In this role, Michael is in charge of leading the global industry marketing programs for the Life Science and Chemical Analysis market segments, which includes pharma and biopharma as well as the food, chemical, environmental and forensics application space. Michael is based at the LPAD-LSG Division in Waldbronn, Germany. He has held multiple management positions on a European as well as global level, both in the area of Software/Information Management and chemical / pharmaceutical analysis.

Michael holds a PhD in Biochemistry from the DSHS in Cologne, Germany. Prior to joining HP/Agilent as an application specialist for chromatography and mass spectroscopy in 1991, he worked in the IOC accredited dope control laboratory for Prof. Dr. Manfred Donike in Cologne, Germany. Here he gained in-depth practical experience in trace level analysis of performance enhancing substances in routine analysis and international research projects.
The pharmaceutical industry faces constant challenges, as business, science, and regulatory pressures evolve and collide. From personalized medicine, to CROs, the process of bringing drugs to market today is dramatically changing. At Agilent Technologies, we have developed a comprehensive portfolio of measurement platforms to help you achieve success in pharmaceutical industry for a long time. From Agilent pharmaceutical compliance summit, you can learn how you can prepare your lab environment to meet recent pharmaceutical compliance guidelines with Dr. Ludwig Huber. Also, you can identify Agilent pharmaceutical compliance-ready solutions using chromatography and lab software technology.

Date: 10 April 2013 (Wednesday)
Venue: Sunway Resort Hotel & Spa
Kay West Room at Level 10, Kuala Lumpur, Malaysia

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