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SPEAKERS

ARJAN BANNINK
Waters, The Netherlands

ULLA BONDEGAARD
Novo Nordisk, Denmark

PETER J. BOOGAARD
Industrial Lab Automation, The Netherlands

DR MARKUS DATHE
F. Hoffmann-La Roche, Switzerland

MICHAEL GOETTER
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CORNELIA HOROIU
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MSD, The Netherlands

DR FERDINAND STEIERHOFFER
Boehringer Ingelheim Pharma, Germany

Laboratory Informatics – Update 2015

cGMP Compliance Trends in Analyical Quality Control

Düsseldorf/Neuss, Germany
10-11 November 2015

HIGHLIGHTS:

Laboratory Informatics

- Similarities, Differences and Potential of Different Applications like LIMS, ELN, PLM, ERP, etc.
- Regulatory Requirements (EU and US)
- Hot Topic: Lab Data Integrity
- Practical Handling of COTS Laboratory Computerised Systems
- Implementation and Validation of Lab Standard Systems - a risk-based Approach
- Lab Systems – Going Paperless
- Lab Data Integrity – Water's Approach for QA/QC
- From Instruments to Decisions

cGMP Compliance Trends in Analytical Quality Control

- New GMP Requirements for the Analytical Lab: EU GMP Chapter 5 & 6 and the New FDA Guidance July 2015
- Regulations on Elemental (Metal) Impurities
- Update on the status of the USP, FDA and ICH guidelines
- Path forward at Merck & Co.
- New USP Chapter <1029> Good Documentation Guidelines - Impact on the Analytical Laboratories
- Chemical Reference Standards for Quality Control
- Expiry Dating for Chemicals, Reagents, Solutions, and Solvents
- Interface Method Development - Validation
- Case Study: Handling of OOT Results
- Automation in QC Labs / Efficient Documentation

Laboratory Informatics – Update 2015

Objectives

It is the aim of this Conference to discuss the different applications of LIMS, ELN, LES, SDMS, PLM, ERP, etc. and to show how Laboratory Datamangement Systems can be implemented in today's QC and R&D environment. Technical issues will also be addressed, e.g. how to connect analytical instruments, or how to integrate Electronic Laboratory Notebooks (ELNs) and LIMS.

Effective validation of Lab Standard Systems will be another focus area of this course. Approaches to paperless laboratories will show how close analytical labs can get there today. A team of experienced speakers will provide you the opportunity to learn more about their practical experiences and to discuss possible pitfalls and how to avoid these.

Background

The paperless laboratory has been a dream in QC and R&D for a number of years. It offers the possibility to improve and accelerate the analytical processes in the laboratory on one hand, and to save money and costs on the other hand.

The power of a paperless lab is the ability to enable organizations to implement self-documenting processes that produce GxP-compliant documentation which eliminates unnecessary tasks from the workflow, resulting in a significant reduction of the cost of non-compliance and optimization of the corporate Cost of Goods Sold (COGS).

But the integrity and security of laboratory data, records, results, and information is fundamental for running a successful GMP regulated QC laboratory. This applies for the classic analytical lab as well as for microbiology or other labs both, for in-house labs or contract labs.

To develop a secure, stable and "validable" laboratory information management system (LIMS) - maybe even compatible with an already existing system - is a real challenge for LIMS suppliers. And the successful implementation and validation of lab data systems in compliance with GAMP and GMP requirements (EU Annex 11, US 21 CFR Part 11, PIC/S, etc.) is a huge challenge for all pharmaceutical QC and R&D departments.

This year's hot topic is lab data integrity, driven by regulatory requirements (FDA Pre Approval Inspections, MHRA Guidances, etc.) resulting in many citations in FDA warning letters and also after inspections of European authorities.

Moderator

Peter J. Boogaard, *Industrial Lab Automation, The Netherlands*

Target Audience

This conference is aimed at the following attendees:

- Laboratory personnel working in GMP laboratories in the pharmaceutical industry, contract research organisations, contract manufacturing organisations and API manufacturers
- Employees involved in the implementation and use of LIMS
- Quality Assurance /Quality Control (Quality Manager, Quality Systems Project Leader, Laboratory Head, QA Director)
- Lab Information Management
- ELN and LIMS Project Leader
- IT, Informatics and Support
- LIMS Suppliers

Social Event

On the evening of the first congress day, on 10 November 2015, all congress delegates and speakers are invited to a „Get together" in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

Programme

Similarities, Differences and Potential of Different Applications like LIMS, ELN, SDMS, PLM, ERP, etc.

- Positioning LIMS, ELN, ERP, PLM and LES solutions:
  - What is an ELN? What function does it serve? Where does it fit within my laboratory informatics strategy?
  - Do we need an ELN or LIMS? And if so what would be best to deploy?
  - What about ERP and PLM? When to use an ELN, LIMS or both?
- How to manage single point of truth in a complex IT landscape
- Strategies to integrate and consolidate

PETER J. BOOGAARD, *Industrial Lab Automation*

Implementation and Validation of Lab Standard Systems - a risk-based Approach

- What make Standard Lab Systems special?
- How to use risk based approaches to ease validation burdens
- CSV in the regulated lab environment – it is all about the data
- Implications of new lifecycle process validation guides to CSV and lab system requirements
- Multi-V approach for large implementations
- The supplier's role in standard systems
- CSV and equipment qualification integration – is it possible?

DR MARKUS DATHE, *F. Hoffmann-La Roche*

Regulatory Requirements Update (EU and US)

- Update of regulatory requirements and guidelines:
  - FDA: 21 CFR Part 11
  - EU: Annex 11
  - GAMP guidelines
- How to apply these rules in new IT structures
- New FDA's One Quality Voice initiative
- Self documenting processes: new concepts to capture analytical instrument data
- How to deal with a hybrid/paper/electronic system?

PETER J. BOOGAARD, *Industrial Lab Automation*

Lab Systems - Going Paperless

- Pre-requisites and drivers of going paperless
- Do's and Don'ts of electronic workflows
- Does electronic mean paperless?
- The pharma lab in the age of QbD – can we still work on paper? - Common misunderstandings
- Infrastructure considerations

DR MARKUS DATHE, *F. Hoffmann-La Roche*

Hot Topic: Lab Data Integrity

- Regulatory background and recent challenges
- Hype or known problem?
- How to analyse the current state and possible need for action
- Audit trail review in the context of data integrity
- And what about the paper?

DR MARKUS DATHE, *F. Hoffmann-La Roche*

Trending, Data Integrity and Regulatory Guidance – Why QC Needs Paperless Informatics Tools Now

- How recent regulatory and industry guidance in adverse trending and data integrity for QC organizations increases the demand for paperless labs and major improvements in analytical tools
- Recent regulatory guidance in adverse trending of data (USP <1116>, etc.)
- Data integrity between lab instruments and software
- The need to look beyond the lab at a completely "paperless" sample lifecycle

MICHAEL GOETTER, *Lonza Bioscience*

Challenge Lab Data Integrity - Water's Approach for QA/QC

- How to safeguard your laboratory data?
- Three keys to scientific data management; Data Retention, Data Integrity and Traceability

ARJAN BANNINK, *Waters*

From Instruments to Decisions, Unifying and Integrating Laboratory Informatics

- Importance of an integrating knowledge engineering system of a modern laboratory which combines Enterprise Content Management with a modern Multi-Vendor Instrument Management of an Chromatographic Data System (CDS)
- Instant access to all available information and the automation of the business
- Actual OpenLAB Suite of Agilent Technologies

HEIKO LINDE, *Agilent Technologies*

cGMP Compliance in Analytical Quality Control

Objectives

It is the aim of this course to address all those GMP Compliance issues that are currently discussed as hot topics in analytical quality control laboratories and during GMP-/FDA-Inspections. This course will give an update about the actual regulatory requirements (EU, US, WHO, etc.) and will show how these requirements can be put into practice. In addition this course will look at scientific and regulatory trends to be expected in the future.

Background

Due to changing regulatory requirements pharmaceutical quality control units are continuously facing new challenges. There are many regulatory requirements relevant for the pharmaceutical quality control, both in EU and in the US, for instance EU GMP Guide, 21 CFR Part 210/211 (USA), EMA and FDA Guidances, WHO Recommendations and Pharmacopoeias (Ph.Eur., USP, JP).

Laboratory Managers and Analytical Scientists must be familiar with all these GMP-related topics and must be aware of the latest updates and the current interpretation of all these guidance documents.

In addition, analytical QC laboratories are increasingly in the focus of GMP inspections, both in Europe and in the US. For instance after FDA inspections, many laboratory-specific citations can be found in 483s and Warning Letters. And many findings related to the laboratory can also be found after inspections of European GMP supervisory authorities. It is thus the aim of this conference to address these topics in detail that are crucial for GMP compliance during regulatory inspections.

Topics of the conference are:

- New GMP Requirements for the Analytical Lab: EU GMP Chapter 5 & 6 and the new FDA Guidance July 2015
- New USP <1029> Good Documentation Chapter - Impact on Laboratories.
- Handling of OOT Results as new requirement in EU GMP Chapter 6 – how to realize in practice?
- Chemical Reference Standards for Quality Control
- Expiry Dates for Reagents, Solvents, Solutions, ...
- Interface Method Development - Validation
- Automation in QC Labs / Efficient Documentation

Moderator

Frans Maris, *MSD, Oss, The Netherlands*

Target Audience

This conference will be of significant value to

- Laboratory managers
- Quality control managers
- Qualified Persons (QPs)
- Analytical scientists
- Senior laboratory staff

from quality control units in the pharmaceutical industry (routine QC and in research and development) who are responsible for GMP Compliance in the analytical laboratory. This course is also intended for employees in Quality Assurance and from contract labs

Programme

New GMP Requirements for the Analytical Lab: EU GMP Chapter 5 & 6 and the New FDA Guidance July 2015

- New EU GMP Chapter 5 – relevant parts for QC labs
- New EU GMP Chapter 6 Quality Control
- Final FDA Guidance for Industry from July 2015 - Analytical Procedures and Methods Validation for Drug and Biologics

ULLA BONDEGAARD, *Novo Nordisk*

New USP Chapter <1029> Good Documentation Guidelines - Impact on the Analytical Laboratories

- General principles of good documentation
  - How much should the laboratory record?
- Documentation related to laboratory equipment
  - Does the laboratory need more than a log book?
- The analytical procedure
  - What is the purpose and contents of analytical procedures?
- Protocols and reports
  - When do the laboratory write a protocol and report?
- Paper records versus electronic records
  - Where are the laboratories going?

ULLA BONDEGAARD, *Novo Nordisk*

Chemical Reference Standards for Quality Control

- Reference standards as QC key factors
- Terminology for reference standards:
  - Primary Standard (PS)
  - Secondary Standards (SS)
  - Reference Materials (RM)
- Regulatory requirements
- Tests for qualification: traceability / equivalency
- The use of reference standards at UCB
- Global management of reference standards at UCB:
  - Distribution
  - Storage conditions

CORNELIA HOROIU, *UCB Pharma*

Interface Method Development - Validation (Focus: Dissolution Testing)

- Pharmacopoeial and regulatory recommendations on analytical method development
- Importance of analytical methods in development stability studies
- Points to consider during method development (Dissolution)
- Requirements for method validation
- Validation characteristics – update of USP chapter <1092>
- Typical pitfalls within interaction of method development and validation

DR FERDINAND STEIERHOFFER, *Boehringer Ingelheim*

Regulations on Elemental (Metal) Impurities: Update on the Status of the USP, FDA and ICH Guidelines
Path forward at Merck & Co.

- Summary of ICH Q3D guideline on elemental impurities
- Harmonization with USP, FDA, EP and other countries
- Risk assessment
- Controling Drug product vs sources of elemental impurities (e.g. API, excipient)
- Analytical Technologies
- Approach at Merck & Co (MSD in Europe)
- Life cycle management

FRANS MARIS, *MSD*

Case Study: Handling of OOT Results

- Methods on performing trend analysis and handling OOT results on
  - release results
  - stability results
- Systems for data evaluation
- Practical approaches

LISELOTTE KAMPER, *Novo Nordisk*

Expiry Dates for Reagents, Solvents, Solutions, ...

- Regulatory requirements
- Approaches to establish an expiry date
- Practical examples from current activities

CORNELIA HOROIU, *UCB Pharma*

Automation in QC Labs / Efficient Documentation

- Objectives of automation
- Examples for automation
- The paperless QC-(lab)process
- Traditional LIMS vs. automated lab processing and reporting

DR FERDINAND STEIERHOFFER, *Boehringer Ingelheim*

Speakers

ARJAN BANNINK, *Waters , The Netherlands*
Analytical Chemist worked in commercial role together with pharmaceutical companies to solve their analytical challenges and optimize their workflow processes for the last 15 years. Current role is to drive adoption of the Laboratory Management Software Solutions from Waters in QC departments from key accounts within Europe.

ULLA BONDEGAARD, *Novo Nordisk, Bagsværd, Denmark*
Ulla Bondegaard (M.Sc. Chemical Engineering) has many years of experience in management of quality control laboratories covering a wide range of analytical techniques (HPLC, GC, AAS, AA, IR, Elisa, etc.). Currently she is responsible for maintaining cross-organisational (and cross-country) laboratory processes in Novo Nordisk, including general laboratory GMP, handling of laboratory computerised systems and transfer of analytical procedures.

PETER J. BOOGAARD, *Industrial Lab Automation, The Netherlands*
Peter Boogaard has extensive experience in laboratory management to enable cross-functional collaboration between research, development, quality assurance and manufacturing corporations. Peter is founder of Industrial Lab Automation. He is publishing in international magazines and contributes in several industry advisory boards. Peter is Dutch citizen and studied analytical chemistry in Delft.

DR MARKUS DATHE, *F. Hoffmann-La Roche AG, Basel, Switzerland*
Analytical and Process Chemist, more than 20 years of practical experience in laboratory, quality and informatics functions. Markus held several positions in life science and pharma operations of Novartis since 1997, joined Siegfried in 2006 and is GMP and CSV coordinator in the chemical development and supply of Hoffmann-La Roche in Basel since 2011. He has been successfully leading global projects like CDS, LIMS, QMS.

MICHAEL GOETTER, *Lonza Bioscience*
Mike Goetter is an expert on automation solutions for quality control within the pharmaceutical industry. Currently General Manager of Informatics for Lonza Bioscience, Mike is responsible for the strategic and operational direction of Lonza's Informatics software portfolio.
As co-founder of MODA Technology Partners, Mike was responsible for the creation of the MODA-EM software platform and driving global market adoption as business development lead. Prior to founding MODA, Mike was co-founder of The Sycamore Group, an information technology consultancy.

CORNELIA HOROIU, *UCB Pharma SA, Belgium*
C. Horoiu has completed a Master Management &Quality Control from University Bordeaux II in France. Since 10 years working in Quality Control UCB Pharma-Belgium, currently in a global position for management of the corporate Critical Materials. During QC activities, various experiences were achieved: product release (DS, DP) dissolution tests, setting specifications (release, stabilities).

LISELOTTE KAMPER, *Novo Nordisk, Denmark*
Liselotte Kamper (M.Sc. Pharm) has worked with several issues regarding handling of Out-Of-Trend results from stability studies for the last 15 years and a system for following trends on release results of drug products. She is also the author of Novo Nordisk internal procedure for handling of OOT results in stability studies.

DIPL. ING. HEIKO LINDE, *Agilent Technologies, Waldbronn, Germany*
Heiko Linde started as lab technician, after studying chemistry with a focus on instrumental analytics, he worked for a big pharma company in the validation area for lab and production. After that he worked as Service Technician for GC, GCMS, etc.. Finally he moved over as Product Specialist for Informatics doing implementations, sales and support of networked CDS, LIMS, archiving and spectral data handling solutions with national as well as international responsibilities. Since 2005 as Sen. Sales Product Specialist responsible for Lab informatics at Agilent Technologies Germany.

FRANS A. MARIS, *MSD, Oss, The Netherlands*
Frans Maris started at Organon in 1987 and was in charge of several analytical laboratories involved in pharmaceutical analysis, bioanalysis, as well as Quality Control. Later he was appointed to general manager of an Organon analytical site in Germany. In 2004 he was made responsible for the department Investigational Products Supply at Organon in the Netherlands. Since September 2007, Frans Maris returned to Germany as site Manager of the analytical laboratories. In 2009 the site became part of the MRL Network of Merck/MSD and was divested in 2011. After that Frans Maris returned to MSD, NL, and is now head of the Quality Control Analytical Chemistry laboratories for finished products. In 2015 he was appointed as global Merck/MSD project lead for the implementation of ICH Q3D guideline on elemental impurities.

DR FERDINAND STEIERHOFFER, *Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany*
Dr Ferdinand Steierhoffer is a pharmacist by training and conducted his PhD at the Martin-Luther-University Halle-Wittenberg in cutaneous gene therapy. Dr Steierhoffer joined Boehringer Ingelheim Pharma GmbH & Co. KG in 2007 where he started in the quality control department. He is currently heading a dissolution lab within the Analytical Development Department at Boehringer Ingelheim in Biberach and acts as a deputy head of quality control for investigational medicinal products.

Agenda

Time	Laboratory Informatics – Update 2015 Tuesday, 10 November 2015	cGMP Trends in Analytical Quality Control Wednesday, 11 November 2015	Time
9.00 h	Welcome and Introduction	Welcome and Introduction	9.00 h
9:15 h	Similarities, Differences and Potential of Different Applications like LIMS, ELN, SDMS, PLM, ERP, etc. *Peter J. Boogaard, Industrial Lab Automation*	New GMP Requirements for the Analytical Lab: EU GMP Chapter 5 & 6 and the new FDA Guidance July 2015 *Ulla Bondegaard, Novo Nordisk, Denmark*	9:15 h
9.30 h			9.30 h
9:45 h			9:45 h
10.00 h	Implementation and Validation of Lab Standard Systems - a risk-based Approach *Dr Markus Dathe, F. Hoffmann-La Roche*	Chemical Reference Standards for QC *Cornelia Horoiu, UCB Pharma SA, Belgium*	10.00 h
10:15 h			10:15 h
10.30 h			10.30 h
10:45 h	Break *(Take advantage of the break to visit the exhibition)*	Break *(Take advantage of the break to visit the exhibition)*	10:45 h
11.00 h			11.00 h
11:15 h			11:15 h
11.30 h	Regulatory Requirements (EU and US) *Peter J. Boogaard, Industrial Lab Automation*	New USP Chapter <1029> Good Documentation Guidelines - Impact on the Analytical Laboratories *Ulla Bondegaard, Novo Nordisk, Denmark*	11.30 h
11:45 h			11:45 h
12.00 h			12.00 h
12:15 h	Lab Systems - Going Paperless *Dr Markus Dathe, F. Hoffmann-La Roche*	Interface Method Development - Validation *Dr Ferdinand Steierhoffer, Boehringer Ingelheim*	12:15 h
12.30 h			12.30 h
12:45 h			12:45 h
13.00 h	Lunch Break *(Take advantage of the break to visit the exhibition)*	Lunch Break *(Take advantage of the break to visit the exhibition)*	13.00 h
13:15 h			13:15 h
13.30 h			13.30 h
13:45 h			13:45 h
14.00 h			14.00 h
14:15 h			14:15 h
14.30 h	Hot Topic: Lab Data Integrity *Dr Markus Dathe, F. Hoffmann-La Roche*	Regulations on Elemental (Metal) Impurities *Frans Maris, MSD*	14.30 h
14:45 h			14:45 h
15.00 h			15.00 h
15:15 h	Break *(Take advantage of the break to visit the exhibition)*	Break *(Take advantage of the break to visit the exhibition)*	15:15 h
15.30 h			15.30 h
15:45 h			15:45 h
16.00 h	Trending Data Integrity and Regulatory Guidance- Why QC Nees Paperless Informatics Tools Now *Michael Goetter, Lonza Bioscience*	Case Study: Handling of OOT Results *Liselotte Kamper, Novo Nordisk*	16.00 h
16:15 h			16:15 h
16.30 h			16.30 h
16:45 h	Challenge Lab Data Integrity - Water's Approach for QA/QC *Arjan Bannink, Waters*	Expiry Dates for Reagents, Solvents, Solutions, ... *Cornelia Horoiu, UCB Pharma*	16:45 h
17.00 h	From Instruments to Decisions, Unifying and Integrating Laboratory Informatics – *Heiko Linde, Agilent Technologies*		17.00 h
17:15 h	Final Discussion	Automation in QC Labs / Efficient Documentation *Dr Ferdinand Steierhoffer, Boehringer Ingelheim*	17:15 h
17.30 h			17.30 h
17:45 h		Final Discussion	17:45 h
18:00 h			18:00 h
18.30 h	Social Event for Congress Delegates, Speakers and Exhibitors		18.30 h

Easy Registration

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Dates
Tuesday, 10 November 2015, 09.00 – 18.00 h
Wednesday, 11 November 2015, 09.00 – 18.00 h
(Registration Monday, 9 November, 19.00 – 20.30 h and
Tuesday, 10 November/Wednesday, 11 November 08.00 – 09.00 h)

Venue
Swissôtel Düsseldorf / Neuss
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Fees
€ 690,- (€ 345,- for EU GMP Inspectors) for one day ticket plus VAT
€ 1.380,- (€ 690,- for EU GMP Inspectors) for two days ticket plus VAT

The conference fee is payable in advance after receipt of invoice and includes lunch on that day/on both days as well as beverages during the event and during breaks. It also includes the Social Event on the evening of the first congress day. VAT is reclaimable.

Your registration also entitles you to participate in all other PharmaLab Congress conferences during the day of your conference/during the two days. For information on all PharmaLab conferences please visit **www.pharmalab-congress.com**.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.pharmalab-congress.com

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Please note that there will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center.

Please further note that there will be no room reservations via Concept Heidelberg. Please book your **hotel room directly with the reservation form** which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.

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☐ 1-Day Ticket (10 or 11 Nov.) – € 690,- ☐ 2-Days Ticket (10 and 11 Nov.) – € 1.380,-
I would like to attend the following conference(s):
☐ **Laboratory Informatics – Update 2015** (10 November 2015)
☐ **cGMP Compliance Trends in Analytical Quality Control** (11 November 2015)

☐ Yes, I will participate in the Social Event on 10 November.
☐ Mr ☐ Ms

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