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cGMP Compliance Trends in Analyical Quality Control

Laboratory Informatics – Update 2014

Düsseldorf/Neuss, Germany
19-20 November 2014

SPEAKERS

DR PAOLA BERIN
F.I.S., Milano, Italy

ULLA BONDEGAARD
Novo Nordisk, Bagsværd, Denmark

DR ALINE GAUFFRE
Lilly France, Illkirch, France

DR FRANS A. MARIS
MSD, Oss, The Netherlands

ERIC DE MAESSCHALCK
UCB, Brain, Belgium

DR BOB MCDOWALL
McDowall Consulting, Bromley, Kent, UK

DR HERBERT WEINDORF
Sandoz International, Frankfurt, Germany

DR ROBERT WEISS
Baxter, Vienna, Austria

HIGHLIGHTS:

cGMP Compliance Trends in Analytical Quality Control

- Recent Changes in US Law, FDA Enforcement and USP
- Handling of OOE and OOT Results, including OOT Results in Stability Testing
- New FDA Requirement: Expiry Dates for Chemicals, Reagents, etc.
- GMP and Quality Oversight in QC Laboratories
- Transfer of Analytical Procedures: which Guideline to follow?
- Reducing Foreign Matter in Pharmaceutical Products: Analytical Challenges
- New FDA Methods Validation Draft Guidance
- Raw Data and Complete Data in EU and FDA Regulations

Laboratory Informatics

- Data Standards for Analytical Instruments: Where have we come from and where are we going?
- Hot Topic in EU GMP Annex 11 – Audit Trails
- Designing Paperless Lab Data Processes and Compliance through Implementation of integrated e-Analytics @ UCB
- The Role of Chromatography Data Systems in QC Laboratory Data Falsification Cases
- LIMS Customisations in QC Labs and Connection with Site MES and ERP Systems
- LIMS Validation – key Issues of Project Phases

cGMP Compliance in Analytical Quality Control

Objectives

The aim of this course is to address hot topics in GMP Compliance that impact analytical quality control laboratories including 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.

Background

Owing 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.

Topics that will be addressed include

- Recent Changes in US Law, USP General Chapters and FDA & MHRA Enforcement
- Handling of OOT Results as new requirement in EU GMP Chapter 6 – how to realize in practice?
- Hot topics in GMP Compliance inspections in analytical labs
- New FDA requirements on the stability of reagents, solutions, etc.
- Transfer of analytical methods – how to comply with all the latest guidelines?
- New FDA Draft Guideline on Method Validation (February 2014) – what are the key requirements?
- Increased Focus on Reducing Foreign Matter in Pharmaceutical Products: Analytical Challenges
- Raw Data and complete data in EU and FDA regulation
- MHRA expectations for data integrity

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.

Social Event

On the evening of the first congress day, on 19 November 2014, 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

Recent Changes in US Law, USP General Chapters and FDA Enforcement

- Changes to the FD&C Act 2012 and the impact on FDA inspections
- USP stimulus to the revision process for analytical procedure development and validation
- Impact of CPG 7346.832 for Pre-Approval Inspections of the QC laboratory for data integrity

DR BOB MCDOWALL, *McDowall Consulting, UK*

Case Study: Handling of OOT Results

- Monitoring and Trending in the manufacturing of Plasmaproducts as an important tool for process control
- Handling of Out of Trend (OOT) and/or Out of Expectation Results in retrospective process monitoring
  - during retrospective process monitoring
  - at real-time monitoring at In-Process Control (IPC) tests
- OOT Results in Stability Testing

DR ROBERT WEISS, *Baxter, Vienna*

Case Study: Hot Topics in QC Laboratories

- "Validation" vs "Scientifically Sound" – what's the difference?
- Reagent Stability, an evergreen for GMP audits
- New requirements according to FDA's cGMP Q&As regarding the establishment of expiry dates for chemicals, reagents, solutions and solvents
- Reference Standards of Biological Test Systems – what is expected?
- Invalid test results – do you care?
- OOS and Reportable Values

DR ROBERT WEISS, *Baxter, Vienna*

GMP and Quality Oversight during Audits and Inspections in QC Laboratories

- Laboratories – Walk-Through Tour
- GMP-Traceability in Labs
- Statistical Calculation, Trend Evaluation and Source Data Management

DR HERBERT WEINDORF, *Sandoz International*

Guidelines regarding Transfer of Analytical Procedures

- Everyone issues guidelines about transfer of analytical procedures – What's in all these guidelines?
- USP <1224>, EU GMP Chapter 6, ISPE, PDA and WHO
- A practical way of complying with all these guidelines

ULLA BONDEGAARD, *Novo Nordisk, Denmark*

Increased Focus on Reducing Foreign Matter in Pharmaceutical Products: Analytical Challenges

- Foreign or extraneous matter
- Requirements and expectations from authorities
- Experiences with Japanese authorities
- Investigation step 1: identification of foreign matter
  - Microscopy, pictures and library
  - IR-microscopy for organic material
  - SEM-EDX and ICP-AES for inorganic material
- Step 2: participation in Root Cause Analysis
- Step 3: preventing foreign matter

DR FRANS MARIS, *MSD, The Netherlands*

New FDA Draft Guidance: Analytical Procedures and Methods Validation for Drugs and Biologics (Feb: 2014) – Requirements and Challenges

- What's new compared to the FDA 2000 draft guidance
- Impact on the daily work in the laboratory

ULLA BONDEGAARD, *Novo Nordisk, Denmark*

What are Raw Data and Complete Data in EU and FDA regulations?

- What does FDA GMP "complete data" mean?
- What does EU GMP "raw data" mean?
- Are raw data and complete data the same?
- How can I define complete data and / or raw data for a system?
- Can paper still be considered the primary record for hybrid systems?

DR BOB MCDOWALL, *McDowall Consulting, UK*

Laboratory Informatics – Update 2014

Objectives

It is the aim of this Conference to discuss the different applications of LIMS, ELN, SDMS, ERP, etc. and to show how informatics solutions can be implemented in today's QC and R&D environment. Technical issues will also be addressed, e.g. how to automatically check instruments, reagents and solutions status during analysis, how to connect analytical instruments, or how to interface instruments to informatics applications.

LIMS project issues will be another focus area of this course. A case study will show how close analytical labs can get to a paperless laboratory 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, ensure compliance 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.

Data integrity and security of laboratory 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.

Regulatory requirement for record retention means that lab data must be stored for a minimum of 5 years, often much longer. Systems and hardware change but the data do not! Currently data file formats are proprietary meaning that the system you acquired the data on must be available for reprocessing. Open data standards are essential and a presentation will look at progress in the area.

Topics that will be addressed are:

- Data Standards for Analytical Laboratories
- Regulatory requirements – Audit trails as hot topic in EU GMP Annex 11
- Importance of laboratory data integrity
- Designing paperless lab data processes and compliance through implementation of integrated e-Analytics
- Moving from standalone data systems to paperless operation
- The role of chromatography data systems in QC laboratory data falsification cases (and how to prevent this)
- Connecting a LIMS to Site MES and ERP systems
- Key project phases of LIMS validation

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 Leaders
- IT, Informatics and Support
- Lab informatics Suppliers

Programme

Data Standards for Analytical Instruments: Where have we come from and where are we going?

- Why do we need data standards?
- Previous data standards efforts
- Problems with older methods of standardisation
- New data standardisation methods

DR BOB MCDOWALL, *McDowall Consulting, UK*

Hot Topic in EU GMP Annex 11 – Audit Trails

- Understanding audit trail requirements
- Comparison with Part 11 audit trail requirements
- Are commercial audit trails adequate?
- What about audit trail review?

DR BOB MCDOWALL, *McDowall Consulting, UK*

Data Integrity in the QC Laboratory: Changing Mind Set

- Assessment Data Integrity project
- Outcome and learning points
- Change of mindset

DR ALINE GAUFFRE, *Lilly France*

Designing Paperless Lab Data Processes and Compliance through Implementation of integrated e-Analytics @ UCB

- Automated checking of instruments, reagents and solution status during analysis
- Direct data capture from equipment removes the need for analyst's notebooks
- Moving from standalone data systems to paperless operation through SDMS implementation
- Facilitating APQR preparation through LIMS data extraction

ERIC DE MAESSCHALCK, *UCB, Braine, Belgium*

The Role of Chromatography Data Systems in QC Laboratory Data Falsification Cases (and how to prevent this)

- Examples where CDS have played a starring role in data falsification cases
- Analysis of data falsification cases to find root cause problems
- Ways of preventing data falsification when using a CDS

DR BOB MCDOWALL, *McDowall Consulting, UK*

An Example of LIMS Customisations in QC Lab and its Connection with Site MES and ERP Systems

- System Architecture
- Analytical status management for in-process controls and lots
- Instrument log-book configuration
- Reporting and Certificates generations in compliance with 21 CFR Part 11
- Customization of a web-inferface for same LIMS system

DR PAOLA BERIN, *F.I.S, Milano, Italy*

LIMS Validation – key Issues of Project Phases

- Project – not compliance – risk management
- Role of management
- Phasing the project
- Populating the data base
- Integrating stability data to a new system

DR BOB MCDOWALL, *McDowall Consulting, UK*

Speakers

DR PAOLA BERIN, *F.I.S., Milano, Italy*
Dr Paola Berin has been working in QC labs for a long time. She is experienced in LIMS Customization, analytical instrument qualification and GMP laboratory compliance. She is responsible for lab x-ray powder diffractor and x-rdp evaluation. Paola is also in charge of cleaning validation management.

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.

DR ALINE GAUFFRE, *Lilly France SAS, Illkirch, France*
Dr Gauffre joined Lilly in successive functions in QA, regulatory, process and product engineering support, project leader in multiple product transfer and industrialization. After 2 years in a Black belt (lean 6 sigma) assignment Aline joined the QC as QC manager where she is in charge of the maintenance and qualification of the analytical equipment.

DR FRANS A. MARIS, *MSD, Oss, The Netherlands*
Dr Maris is now head of the Quality Control Analytical Chemistry laboratories for finished products.

ERIC DE MAESSCHALCK, *UCB, Brain, Belgium*
His current position is Head of Global e-Analytics, Corporate Analytical Sciences, where he has to define the long term strategy for electronic analytical tools supporting business processes to be implemented across UCB sites (e.g. GLIMS, ELN, statistical application, central chromatography, scientific data management system, etc.).

DR BOB MCDOWALL, *McDowall Consulting, Bromley, Kent, UK*
Principal of McDowall Consulting, UK. He has been involved with the validation of computerised systems for over 25 years and is the author of a book on the validation of chromatography data systems. Bob is the writer of the Questions of Quality (LC-GC Europe) and Focus on Quality (Spectroscopy) columns and is a member of the Editorial Advisory Boards of several Journals.

DR HERBERT WEINDORF, *Sandoz international, Industriepark Höchst Frankfurt*
Herbert Weindorf is global GMP Auditor within Novartis auditors organization, he is involved mainly with Sandoz Third Party audits and committed with several projects according to QA Compliance activities.

DR ROBERT WEISS, *Baxter AG, Vienna, Austria*
Dr Weiss is Head of Quality Control and responsible for all product release testing. He is acting as Qualified Person, manufacturing products for people with hemophilia, immune disorders and various other acute medical conditions.

Agenda

Time	cGMP Trends in Analytical Quality Control Wednesday, 19 November 2014	Laboratory Informatics – Update 2014 Thursday, 20 November 2014	Time
9.00 h	Welcome and Introduction	Welcome and Introduction	9.00 h
9:15 h 9.30 h 9:45 h	Recent Changes in US Law, USP General Chapters and FDA Enforcement *Dr Bob McDowall, McDowall Consulting, UK*	Data Standards for Analytical Instruments: Where have we come from and where are we going? *Dr Bob McDowall, McDowall Consulting, UK*	9:15 h 9.30 h 9:45 h
10.00 h 10:15 h 10.30 h	Case Study: Handling of OOT Results *Dr Robert Weiss, Baxter, Vienna*	Hot Topic in EU GMP Annex 11: Audit Trails *Dr Bob McDowall, McDowall Consulting, UK*	10.00 h 10:15 h 10.30 h
10:45 h 11.00 h 11:15 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 11:15 h
11.30 h 11:45 h 12.00 h	Case Study: Hot Topics in QC Laboratories *Dr Robert Weiss, Baxter, Vienna*	Data Integrity in the QC Laboratory: Changing the Mind Set *Aline Gauffre, Manager QC Lab, Lilly France*	11.30 h 11:45 h 12.00 h
12:15 h 12.30 h 12:45 h	GMP and Quality Oversight during Audits and Inspections in QC Laboratories *Dr Herbert Weindorf, Sandoz International*	Designing Paperless Lab data processes and compliance through implementation of integrated e-Analytics @ UCB *Eric De Maesschalck, Corporate Analytical Sciences, UCB, Brain, BE*	12:15 h 12.30 h 12:45 h
13.00 h 13:15 h 13.30 h 13:45 h 14.00 h 14:15 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 13.30 h 13:45 h 14.00 h 14:15 h
14.30 h 14:45 h 15.00 h	Guidelines regarding Transfer of Analytical Procedures *Ulla Bondegaard, Novo Nordisk, Denmark*	The Role of Chromatography Data Systems in QC Laboratory Data Falsification Cases (and how to prevent this) *Dr Bob McDowall, McDowall Consulting, UK*	14.30 h 14:45 h 15.00 h
15:15 h 15.30 h 15:45 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 15:45 h
16.00 h 16:15 h 16.30 h	Increased Focus on Reducing Foreign Matter in Pharmaceutical Products: Analytical Challenges *Dr Frans Maris, MSD, NL*	An Example of LIMS Customisations in QC Lab and its Connection with Site MES and ERP Systems *Dr Paola Berin, F.I.S, Spa, Italy*	16.00 h 16:15 h 16.30 h
16:45 h	New FDA Draft Guidance: Analytical Procedures and Methods Validation for Drugs and Biologics (Feb. 2014) – Requirements and Challenges; *Ulla Bondegaard, Novo Nordisk, Denmark*	LIMS Validation: key Issues of Project Phases *Dr Bob McDowall, McDowall Consulting, UK*	16:45 h
17.00 h 17:15 h 17.30 h	What are Raw Data and Complete Data in EU and FDA regulations? *Dr Bob McDowall, McDowall Consulting, UK*		17.00 h 17:15 h 17.30 h
17:45 h 18:00 h	Final Discussion	Final Discussion	17:45 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
Wednesday, 19 November 2014, 09.00 – 18.00 h
Thursday, 20 November 2014, 09.00 – 18.00 h
(Registration Tuesday, 18 November, 19.00 – 20.30 h and
Wednesday, 19 November/Thursday, 20 November 08.00 – 09.00 h)

Venue
Swissôtel Düsseldorf / Neuss
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Fees
EUR 690,- for one day ticket plus VAT
EUR 1.380,- for two days ticket plus VAT

The conference fee is payable in advance after receipt of invoice and includes lunch on that day as well as beverages during the event and during breaks. It also includes the Social Event on the evening of the first congress day (19 November 2014) 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 further information 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

PLEASE NOTE
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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Mr Detlef Benesch (Organisation Manager) at +49-6221/84 44 45, or per e-mail at benesch@concept-heidelberg.de.

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I would like to attend the following conference(s):
☐ **cGMP Compliance Trends in Analytical Quality Control** (19 November 2014)
☐ **Laboratory Informatics – Update 2014** (20 November 2014)
Part of PharmaLab 2014, Düsseldorf/Neuss, Germany, 19-20 November 2014
☐ 2-Days Ticket for entire PharmaLab Congress (19-20 November 2014)

☐ Yes, I would like to participate in the Social Event on 19 November.
☐ Mr ☐ Ms

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