ECA Academy
Your GMP/GDP Information Source

Computerised Systems in Analytical Laboratories
QC Compliance Trends in Analytical Laboratories
Analytical Challenges for Biological Drug Substances and Products

These conferences are part of
2018 PharmaLab Congress & Exhibition
Analytics•Bioanalytics•Microbiology
Düsseldorf, 20/21 November 2018
www.pharmalab-congress.com

SPEAKERS

DR JAN AMSTRUP
Novo Nordisk

DIETER BRILLERT
Wiewelhove

ULLA BONDEGAARD
Novo Nordisk

DR CHRISTOPHER BURGESS
Burgess Analytical Consultancy

SINEAD COWMAN
Lonza

VIKTORIA ENK
VelaLabs

FLORIAN GÖHNER
Vetter Pharma Fertigung,

DR MICHAEL HABERL
Microcoat Biotechnologie

ROB HAHNRATHS
Bayer

DR ALICE HELLWIG
Microcoat Biotechnologie

DR ULRIKE HERBRAND
Charles River Laboratories

DR HILTRUD HORN
Horn Pharmaceutical Consulting

TEJS KYHL
ALK-Abelló

KYRILLOS KYRIOSOGLOU
Roche Diagnostics

DR FRANK SIELAFF
Regional Authority Darmstadt

ANDREAS STEINLE
Roche Diagnostics

KLEMENS WEITENTHALER
VelaLabs

20/21 November 2018, Düsseldorf/Neuss, Germany

HIGHLIGHTS:

- Computerised Systems in Analytical Laboratories
  - Regulatory Requirements – What are the expectations of an Inspector?
  - The Real Problem – Integration of Existing Instruments to Lab Systems
  - Audit Trail Review
- QC Compliance Trends in Analytical Laboratories
  - Defining and Managing Raw Data
  - Cleaning Validation of Analytical Equipment
  - cGMP Compliance Trends in Analytical Labs
  - Brexit: What is the impact for Pharma?
- Analytical Challenges for Biological Drug Substances and Products
  - Bioactivity Determination
  - Potency Assays
  - Host Cell DNA
  - Bioassays and Structural characterisation
  - Technology for Single Molecular Detection

Media Partner:
European Biotechnology
Life Sciences and Industry Magazine
EPR EUROPEAN PHARMACEUTICAL REVIEW

Computerised Systems in Analytical Laboratories

20 November 2018, Düsseldorf/Neuss, Germany

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 LIMS can be implemented in today's QC and R&D environment. Technical issues will also be addressed, e.g. how to integrate "old" systems into current Lab IT. This year the current data integrity challenges in analytical labs will especially be addressed: which are the actual regulatory expectations (WHO, MHRA and FDA) and what are the expectations of a GMP inspector. Practical Data Integrity and Audit Trail Reviews will be other focus areas of this course. A paperless laboratory case study will show how close analytical labs can get there today.

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. 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 a LIMS 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.

Topics that will be addressed are:

- Regulatory Requirements
- Integration of "old" Systems into current Lab IT
- Case Study: Paperless Laboratory Lab Information Management
- Data Integrity for "Dummies" OR Practical Data Integrity
- Audit Trail Review
- Ensuring Data Integrity throughout the Supply Chain
- Integrating Devices and Systems in QC (and Production) to enable Data Driven Decisions

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 20 November 2018, 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.

Speakers

SINEAD COWMAN, *Lonza*
EU Business Development Manager – Informatics.

FLORIAN GÖHNER, *Vetter Pharma Fertigung*
Projectmanager QC.

ROB HAHNRATHS, *Bayer.*
Consultant - QA & Validation Services at Bayer. Co-lead of the GAMP® DACH Audit Trail review working group.

DR DANILO NERI, *PQE*
Validation Project Manager with expertise on Computer System Validation.

DR FRANK SIELAFF, *Regional Authority Darmstadt*
GMP Inspector with focus on Inspection of drug manufacturers and laboratories in Germany and countries outside of the EU.

ANDREAS STEINLE, *Roche Diagnostics*
Manager Digital Solutions in Pharma Technical Development Europe.

Programme

Alternative Microbiological Methods: AstraZeneca's, GlaxoSmithKline's, Johnson&Johnson's and Roche's Global Implementation Roadmap
DR SVEN M. DEUTSCHMANN, *Roche* / **DR PAUL NEWBY,** *GSK*
PHILIP BREUGELMANS, *JnJ* / **MIRIAM GUEST,** *Astra Zeneca*

Programme

20 November 2018

Regulatory Requirements

- Overview of the regulatory framework
- Computerised systems in the context of lab data integrity
- What are the expectations of inspectors?

DR FRANK SIELAFF, *Regional Authority Darmstadt*

The Real Problem - Integration of Existing Instruments to Lab Systems

- Integration layer – A key for efficient data management
- Data availability for data scientists and for all systems (no point to point)
- Faster decisions and changes with an agile approach for legacy systems
- High scalability from a small satellite laboratory to a global company
- High flexibility at lower costs for business
- Independency from the (big) vendors
- Integration of existing lab standards (e.g. AniML) and upcoming standards (e.g. SiLA 2, Allotrope)
- Easier integration of future challenges (e.g. IoT, machine learning and cloud)

ANDREAS STEINLE, *Roche Diagnostics*

Case Study: Paperless Laboratory

- Introduction: a Paperless Laboratory Project in the context of Industry 4.0
- How to set-up, initiate and control a Paperless Lab Project in QC environment
- The sentiment barometer: An introduction on how to keep the good mood by project marketing
- Integration of lab instruments in existing and to-be IT environments and data-sharing between IT systems
- The process of the future: analyze, harmonize and standardize QC Lab Processes

FLORIAN GÖHNER, *Vetter Pharma Fertigung*

Data Integrity for "Dummies" OR Practical Data Integrity

- How to document SMART User Requirements Specifications
- Practical „Fit for Intended Purpose" by example
- How to develop and understand Risk Assessments
- Empower Migration Dos and Dont's

ROB HAHNRATHS, *Bayer*

Audit Trail Review

- Electronic audit trails are one of the key components in achieving compliance with regulatory expectations for data integrity. But are you using them?
- Understand the regulatory requirements for audit trail review
- Know when to perform audit trail reviews in the QC laboratory
- Learn the added benefits of knowing your audit trail
- Simplify audit trail reviews by searching your audit trail and know what to look for

TEJS KYHL, ALK-Abelló

Ensuring Data Integrity throughout the Supply Chain

- Regulatory authorities became focused more and more on Data Integrity and regulated companies are required to strictly ensure Data Integrity throughout the data lifecycle
- Overarching Data Governance to be established through a Corporate Data Integrity Program and to be addressed and monitored at each site
- Implementation of guidance documentation to ensure the compliance for each GxP records either created by the company or acquired by a supplier (e.g. CMO, Contract Testing Laboratory, CRO).
- Regular risk reviews of supply chains and outsourced activity to evaluate the extent of data integrity controls required
- Enhanced Supplier Qualification process to ensure the reliability of the GxP Data provided to the regulated company
- Verification strategy to assess the current practices for regulated electronic and paper records
- Monitoring of the level of Data Integrity compliance through supplier oversight and follow up

DR DANILO NERI, *PQE*

Integrating Devices and Systems in QC (and Production) to enable Data Driven Decisions

- How to connect devices and systems to derive value from the data they generate and error proof your workflows and processes based on client examples
- Technical and business process considerations for interfaces
- Understanding raw data and determining what data belongs in what system
- Data Integrity compliance
- Review by exception

SINEAD COWMAN, *Lonza*

QC Compliance Trends in Analytical Laboratories

21 November 2018, Düsseldorf/Neuss, Germany

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. Many laboratory-specific citations can be found after inspections of European GMP supervisory authorities in EU Non-GMP Compliance Reports or after FDA inspections in 483s and Warning Letters. Currently the status of FDA inspections and the impact for analytical labs is of great importance. Discuss with us the future of FDA inspections in the light of the MRA and get some understanding what this means for your QC labs.

Furthermore the uncertainty about the consequences of the Brexit for the pharmaceutical industry is a huge challenge for all QC Mangers and QPs. Get some insights what this means for manufacture, testing and release as of 30 March 2019 and how to get prepared for these changes.

Topics that will be addressed are:

- Guidelines developed by the ECA QC Group
  - OOS
  - OOE/OOT
  - Data Governance (with the IT Group)
  - Analytical Procedures Lifecycle Management (QbD for Analytical Methods)
- Cleaning Validation for Analytical Equipment – what are the regulatory expectations today and how to implement in your lab?
- cGMP Compliance Trends
- Defining and Managing Raw Data
- Current Trends and Future of FDA Inspections (MRA)
- Training in QC

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 working in contract labs being involved in development of methods, control testing and Quality Assurance

Speakers

DIETER BRILLERT, *Wiewelhove*
Dieter Brillert is Head of Quality Control within Wiewelhove, a medium-sized CMO, focused on solid oral dosage forms.

ULLA BONDEGAARD, *Novo Nordisk*
Ulla Bondegaard is responsible for maintaining cross-organisational (and cross-country) laboratory processes in Novo Nordisk, including general laboratory GMP, sampling and transfer of analytical procedures.

DR CHRISTOPHER BURGESS, *Burgess Analytical Consultancy*
Chairman of the ECA Analytical Quality Control Working Group. Qualified Person in the EU. Member of the USP Expert Panel on Validation and Verification entrusted to revise General Chapters.

DR HILTRUD HORN, *Horn Pharmaceutical Consulting*
Managing director of HORN PHARMACEUTICAL CONSULTING with focus on CMC, GMP and Regulatory Affairs (EU and US).

TEJS KYH, *ALK-Abelló*
Senior Chemist, Laboratory Automation Development. Heads a team of specialists within data integrity and computerized systems validation in the QC laboratories.

DR FRANK SIELAFF, *Regional Authority Darmstadt*
GMP Inspector with focus on Inspection of drug manufacturers and laboratories in Germany and countries outside of the EU.

Programme

21 November 2018

ECA Analytical Quality Control Group: Aims, Achievements and Activities

GUIDELINES DEVELOPED BY THE ECA QC GROUP

- Structure within ECA Foundation
- Aims and objectives of the AQCG
- Guideline Outputs: OOS, OOE/OOT, Data Governance (with the IT Working Group), Analytical Procedure Lifecycle Management (APLM)
- Work program 2018/2019
  - ICH Q2(R1) revision and USP <1220>
  - EFPIA collaboration on stability testing?
  - Sampling and Sample Management Guideline development

DR CHRIS BURGESS, *Chairman of the ECA QC Group*

Current Experiences from GMP Inspections in QC Labs

- Current Focuses of QC GMP Inspections
- Hot topic: Data integrity in QC labs
- "Highlights" from recent inspections

DR FRANK SIELAFF, *Regional Authority Darmstadt*

Cleaning Validation of Analytical Equipment

- Regulatory requirements for cleaning validation of analytical equipment
- Affected analytical procedures
- Significant differences between cleaning validation in production and laboratory
- Disposable equipment vs. cleaning of reusable equipment
- Example from experience: Cleaning validation of laboratory washing machines

DIETER BRILLERT, *Wiewelhove*

cGMP Compliance Trends in Analytical Labs

- GMP News: What is important for you?
- Brexit: What is the impact for Pharma?
- Compliance: How to ensure compliance and avoid data integrity problems?
- Transfer of methods: What is important?
- ICH Q12 and Life-cycle Management: What are key-aspects for the lab ?

DR HILTRUD HORN, *Horn Pharmaceutical Consulting*

Image: Labor LS

Defining and Managing Raw Data

- Defining electronic and paper-based raw data
- Managing your dataflow
- Selecting proper raw data media
- Archiving electronic raw data

TEJS KYHL, *ALK-Abelló*

Current Trends at FDA and future of FDA Inspections (MRA)

- FDA-Trends and News: What should you consider?
- MRA: What is the status and impact for you?
- Inspections in Labs: How can you successfully prepare for the FDA inspection?
- Practical Examples

DR HILTRUD HORN, *Horn Pharmaceutical Consulting*

Training in QC

- Regulator's expectations for training
- Training that is effective and fit for purpose
- Re-think re-training
- Competency based training
- Examples of training set-up

ULLA BONDEGAARD, *Novo Nordisk*

Analytical Challenges for Biological Drug Substances and Products

21 November 2018, Düsseldorf/Neuss, Germany

Objectives

This Conference will inform you about GMP, GLP and GCLP principles and how they apply to potency Bioassay, limits tests, pharmacokinetics.

You become informed about
- International regulatory requirements
- Current developments of methodology
- Pharmacokinetics
- Biosimilar characterization

Background

The number of biopharmaceutical products is increasing in the clinic and in the market. Their excellent targeting ability is the result of a high complexity. Therefore suitable analytical tests are necessary to ensure the structure and purity of biopharmaceutical drug substances and drug products. But the complexity cannot be measured by analytical tests alone. Therefore, the development process of all biopharmaceutical products requires non-analytical tests to fully evaluate their functionality and safety. Biopharmaceutical development is a multi-disciplinary effort that involves many professionals with diverse backgrounds. This course will help team members without the appropriate technical background by clarifying the timelines, requirements and significance of Bioassays based testing. The types of methods that will be addressed are cell-based assays, immunoassays and molecular assays.

Target Audience

This conference will be of significant value to
- Manufacturing process professionals
- QA/QC staff and regulatory personnel
- Clinical staff, pharmacologists and toxicologists
- Project Managers & outsourcing personnel
- Analytical chemists and biochemists

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 working in contract labs being involved in development of methods, control testing and Quality Assurance

Speakers

DR JAN AMSTRUP, *Novo Nordisk*
Jan is Principle Scientist at Novo Nordisk. Additionally he holds a Black Belt Lean Six Sigma.

VIKTORIA ENK, *VelaLabs*
Viktoria works as a technical expert in the field of mass spectrometry with a focus on protein characterization in a regulated environment.

DR MICHAEL HABERL, *Microcoat Biotechnologie*
Michael is Director Quality Assurance for GLP and GCP services.

DR ALICE HELLWIG, *Microcoat Biotechnologie*
Alice is Director Lab Services at Microcoat.

DR ULRIKE HERBRAND, *Charles River Laboratories*
Ulrike Herbrand works as scientific supervisor for research and development and her focus is mechanism of action reflecting bioassays for protein therapeutics.

KYRILLOS KYRIOSOGLOU, *Roche Diagnostics*
Kyrillos Kyriosoglou is expert for analytsis and Identification and Monitoring of impurities of Biopharmaceuticals, as example Host Cell Proteins by Mass Spectrometry.

KLEMENS WEITENTHALER, *VelaLabs*
Klemens works as a technical expert in the cell culture lab where he is responsible for development and validation of cell-based potency assays.

Programme

21 November 2018

ECA Analytical Quality Control Group: Aims, Achievements and Activities

GUIDELINES DEVELOPED BY THE ECA QC GROUP

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- Work program 2018/2019
  - ICH Q2(R1) revision and USP <1220>
  - EFPIA collaboration on stability testing?
  - Sampling and Sample Management Guideline development

DR CHRIS BURGESS, *Chairman of the ECA QC Group*

What do we need of information from a potency assay?

- Development of Potency assays
- What is needed for the different phases
- Setting SST parameters for Potency assays
- Challenges with specificity

DR JAN AMSTRUP, *Novo Nordisk*

Challenges in Bioactivity Determination

- Bioassays for immune checkpoint mAbs
- Bioassays for mAbs with viral targets
- Bioassays for characterization and lot release of antibody drug conjugates (ADCs)

DR ULRIKE HERBRAND, *Charles River Laboratories*

The interdependence of Bioassays and Structural characterisation

- Potency evaluation using a bioassay: Mode of Action and evaluation models
- Limitations of information gained
- Orthogonal structural characterisation
- How certain modifications impact the Bioassay performance:
  - Deamidations
  - Oxidations
  - Glycovariants
  - Amino Acid Substitutions
- Benefits of interdisciplinary teams in the Biosimilar field (case study)

KLEMENS WEITENTHALER/VIKTORIA ENK, *VelaLabs*

Single Molecular Detection – A new technology

- Background single Molecular detection technology
- Implementation of SIMOA at a contract lab
- Application of SIMOA for ultrasensitive detection of large molecules
- Transfer of a classical ELISA for improvement of sensitivity and comparison to other platforms

DR ALICE HELLWIG, *Microcoat Biotechnologie*

Getting Host Cell DNA analysis up to speed with an automated System

- Host Cell DNA
- Automation
- Performance Qualification

KYRILLOS KYRIOSOGLOU, *Roche*

Development and Validation of an Excel workbook for automated sample information management in the analytical lab

- Setting up and managing a software validation project
- Setting up URS
- Programming and testing
- Routine use
- Benefit over paper based process

DR MICHAEL HABERL, *Microcoat Biotechnologie*

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.pharmalab-congress.com

Dates
Tuesday, 20 November 2018, 09.00 – 18.00 h
Wednesday, 21 November 2018, 09.00 – 18.00 h
(Registration Tuesday, 20 November/Wednesday, 21 November 08.00 – 09.00 h)

Venue
Crowne Plaza Düsseldorf / Neuss
Rheinallee 1
41460 Neuss, Germany
Tel.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
emailus@cphotelduesseldorfneuss.com

Fees (per delegate plus VAT)
19 November 2018: Pre-Conference ,,1st International Mycoplasma qPCR Testing User Day" € 249,-
20 November 2018 € 690,-
21 November 2018 € 690,-

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

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.

Organisation & Contact
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Phone +49 (0) 62 21/84 44-0; Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de; www.concept-heidelberg.de

For questions regarding content:
Dr Günter Brendelberger (Operations Director) at +49-6221/84 44 40, or per e-mail at brendelberger@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at +49-6221/84 44 51, or per e-mail at strohwald@concept-heidelberg.de

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Part of PharmaLab 2018, Düsseldorf/Neuss, Germany, 20-21 November 2018
☐ Pre-Conference, 1st International Mycoplasma qPCR Testing User Day" (19.11.2018 incl. Networking Dinner) - € 249,- plus VAT
☐ Conferences on 20.11.2018 – € 690,- plus VAT
☐ Conferences on 21.11.2018 – € 690,- plus VAT
I would like to attend the following conference(s):
☐ **Computerised Systems in Analytical Laboratories** (20 November 2018)
☐ **QC Compliance Trends in Analytical Laboratories** (21 November 2018)
☐ **Analytical Challenges for Biological Drug Substances and Products** (21 November 2018)

☐ Yes, I will participate in the Social Event on 20 November.
☐ Mr ☐ Ms

Title, first name, surname

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If you cannot attend the conference you have two options:
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2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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