PharmaLab 2018

Analytics, Bioanalytics and Microbiology
– Congress & Exhibition –

Crowne Plaza Düsseldorf/Neuss

20/21 November 2018

www.pharmalab-congress.com

Exhibtor Information in the back of the programme

The Conferences

Put together your own programme:
- nearly 70 Lectures
- over 60 Speakers

19 November 2018

- Pre-Conference Workshop: ECA- 1st International Mycoplasma qPCR Testing User Day

20 November 2018

- ECA – Analytical Procedure Lifecycle Management
  *including Launch of the new ECA APLM Guidance
- ECA – Computerised Systems in Analytical Laboratories
- ECA – Pest Control - from classic trap to digital control
- ECA – Endotoxin and Pyrogen Testing (Day 1)
- ECA – Rapid Microbiological Methods and Mycoplasma Testing

21 November 2018

- ECA – Analytical Challenges for Biological Drug Substances and Products
- ECA - QC Compliance Trends in Analytical Laboratories
- ECA – Endotoxin and Pyrogen Testing (Day 2)

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

40 JAHRE YEARS CONCEPT HEIDELBERG

Pharmaceutical Quality
Training. Conferences. Services.

The Congress Objective

On 20 and 21 November 2018 the PharmaLab Congress will take place in Düsseldorf/Neuss for the sixth time. This Congress addressing staff and executives in all lab areas of the pharmaceutical industry will be comprised of six international and four German language conferences plus the parallel exhibition. It will provide you with current developments of laboratory methods, materials as well as the current status of the regulatory requirements of the Pharmacopoeias.

Furthermore, experts from authorities, industrial quality control and contract laboratories will share their experience with the use and the qualification of analytical systems as well as with the validation of analytical methods and microbiological tests.

Use this unique opportunity to get an update on the state of the art in pharmaceutical laboratories and to discuss current developments with speakers and colleagues.

PharmaLab 2018 Overview

Key Note 20 November
Alternative Microbiological Methods: AstraZeneca's, Johnson&Johnson's, MSD's and Roche's Global Implementation Roadmap
Miriam Guest, AstraZeneca / Philip Breugelmann, JnJ / Marja Claasen, MSD / Dr Sven M. Deutschmann, Roche

Key Note 21 November
ECA Analytical Quality Control Group: Aims, Achievements and Activities
Dr Christopher Burgess, Chairman of the ECA Analytical Quality Control Group

Pre-Conference Workshop Ticket 249,- EUR

19 November 2018

- ECA - 1st International Mycoplasma qPCR Testing User Day

Conferences One day ticket 690,- EUR

20 November 2018

- ECA – Computerised Systems in Analytical Laboratories
- ECA - Analytical Procedure Lifecycle Management
- ECA – Pest Control - from classic trap to digital control
- ECA – Endotoxin and Pyrogen Testing (Day 1)
- ECA – Rapid Microbiological Methods and Mycoplasma Testing

21 November 2018

- ECA – Analytical Challenges for Biological Drug Substances and Products
- ECA – Endotoxin and Pyrogen Testing (Day 2)
- ECA – QC Compliance Trends in Analytical Laboratories

Exhibition (20 and 21 November 2018)

Subject Areas: Analytics | Bioanalytics | Microbiology

Background

Laboratory work is an important part of pharmaceutical research, development and quality control. During inspections the responsible authorities significantly increased their emphasis on the quality management and performance of laboratories and their quality standards. This scrutiny of the regulators require laboratories to establish GLP and GMP appropriate systems and methods, and in particular:

- General GLP or cGMP understanding and particularly relating to compliance with written procedures
- Validation, performance and transfer of analytical procedures and microbial tests
- Validation of analytical methods according to the new USP Lifecycle Model, in particular after the ICH Press Release to update ICH Q2 (R1)
- Computer validation (including the interpretation of EU GMP Annex 11 and 21 CFR Part 11 and the actual requirements for lab data integrity)
- Operator training

Target Group

Especially for pharmaceutical products and active substances from biological origin, classic analytical and testing methods don't fit. New developed methods e.g. MAT for pyrogen testing, rapid methods for sterility testing or necessary bioassays require a permanent knowledge update and advanced training of laboratory personnel and of the involved staff.

This conference will be of interest to

- Laboratory Managers, Supervisors and Analysts in pharmaceutical quality control departments
- Laboratory Staff of Research and Development
- Responsible Authorities
- Suppliers on Laboratories
- Associates of Contract Laboratories

The fees

A one day ticket/two days ticket will enable you to visit the congress (20.11/21.11.2018) either only on day 1 or only on day 2 or on both days. Charges for the one day tickets are € 690,- plus VAT, for the two days ticket € 1.380,- plus VAT. They include lunch and beverages during the conferences and in breaks as well as the social event on the evening of the first congress day (Due to the special fees for the congress, ECA membership discounts are not applicable).
The visit of the pre-conference on 19.11.2018 for € 249,- plus VAT can be combined with the congress (see registrations options on the last page).
A networking dinner is included in the fee. Charges are payable after receipt of invoice.

Particularities of PharmaLab 2018:

- The registration allows you to access the 8 conferences with close to 70 lectures. In a word, you can create your individual conference programme.
- Move any time to any conference room. Thanks to one day tickets, you can attend only the first or the second day - but also both days of PharmaLab.
- You will receive a USB stick including all the conference lectures of the Congress.
- Learn about the latest products and services relating to analytics, bioanalytics and microbiology at the exhibition.
- Take advantage of PharmaLab – and particularly of the Social Event on the evening of the first day – for an information exchange with delegates, speakers and exhibitors.

The 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.

The Location

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

The Organiser

CONCEPT HEIDELBERG – On behalf of the ECA Academy
P.O. Box 10 17 64
D-69007 Heidelberg
Telefon+49 (0) 62 21/84 44-0
Telefax +49 (0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de,
www.gmp-navigator.com

The Contacts

For questions regarding content:
1st International Mycoplasma qPCR Testing User Day / Endotoxin and Pyrogen Testing / Analytical Challenges for Biological Drug Substances and Products / Rapid Microbiological Methods and Mycoplasma Testing / Pest Control – from classic trap to digital control
Axel H. Schroeder (Operations Director), Tel. +49 (0) 6221/84 44 10,
E-Mail: schroeder@concept-heidelberg.de

Analytical Procedure Lifecycle Management / cGMP Compliance Trends in Analytical Laboratories / Computerised Systems in Analytical Laboratories
Dr Günter Brendelberger (Operations Director), Tel.+49 (0) 6221/84 44 40,
E-Mail: brendelberger@concept-heidelberg.de

For questions regarding reservation, hotel, organisation, exhibition etc.:
Ronny Strohwald, (Organisation), Tel.+49 (0) 6221/84 44-51,
E-Mail: strohwald@concept-heidelberg.de

The Media Partner

European Biotechnology
Life Sciences and Industry Magazine

European Biotechnology Magazine reports about the latest political, economic and technical developments in the life sciences sector in all 28 EU countries plus Switzerland and Norway. To find out more please visit www.eurobiotechnews.eu.

EPR

European Pharmaceutical Review is a leading free publication for information about technologies across all stages of drug development. Every issue offers technical and business contributions from the world's leading pharmaceutical companies and experts. Visit www.European-PharmaceuticalReview.com for further information.

Speakers (as of September 2018)	
Dr Jan Amstrup	**Novo Nordisk, Denmark,** Principal Scientist.
Mathilde Arnault	**Merk, France,** Research Scientist - BioMonitoring R&D.
Dr Jürgen Balles	**Labor LS, Germany**, Managing Director.
Dr Alexander Bartes	**Roche Pharma Biotech, Germany,** Senior QC Manager.
Petra Barth	**formerly AbbVie, Germany,** QA Trainer.
Ulla Bondegaard	**Novo Nordisk, Bagsværd, Denmark,** Currently responsible for maintaining cross-organisational (and cross-country) laboratory processes.
Dr Christopher Burgess	**Burgess Analytical Consultancy, UK,** 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 Cornelia Bodinet	**Schaper & Brümmer, Germany,** Head of Division" Pharmaceutical Laboratories".
Dieter Brillert	**Wiewelhove, Germany,** Head of Quality Control within Wiewelhove, a medium-sized CMO, focused on solid oral dosage forms.
Dr Barbara Capecchi	**GSK, Italy,** Senior Manager in Analytical Research and Development.
Martine Caroff	**LPS Bioscience,** Chief Scientific Officer.
Wilmar Correa	**Research Center Borstel, Germany** Chief Scientific Officer.
Sinead Cowman	**Lonza, UK,** EU Business Development Manager – Informatics.
Damian Derincovsky	**Novartis**, MS&T Facilitator BioProduction Operations Huningue, France.
Dr. Sven M. Deutschmann	**Roche Diagnostics, Germany**, Head of Global ASAT "Adventitious Agents Testing and Alternative Microbiologica. Chairman of the Advisory Board of the ECA "Pharmaceutical Microbiology Interest Group", Member of PDA Task Forces.
Silviya Dimitrova	**TEVA Bulgaria,** Member of the ECA QC Group Board and QP. Overall responsibility for quality oversight of European TEVA suppliers as well as QC and QP Release.
John Dubczak	**Charles River Laboratories, France;** General Manager Microbioal Solutions Division.
Dr Markus Fido	**VelaLabs, Austria,** CEO and Founder of VelaLabs. Responsible for Finance & Controlling, Regulatory Affairs & Quality Operations.
Dr Anja Fritsch	**Confarma, France,** Responsible for cell based bioassays (development and routine).
Mario Fusi	**Steriline, Italy,** Technical Director.
Dr Eelo Gitz	**Sanquin Reagents , The Netherlands,** Project manager product development.
Florian Göhner	**Vetter Pharma Fertigung, Germany,** Projectmanager QC.
Tina Grauwet	**SGS Belgium**, Business Unit Manager Pest Management Benelux.
Prof. Dr Rainer Gnibl	**Government of Upper Bavaria, Germany,** GMP Inspector.
Dr Michael Haberl	**Microcoat Biotechnologie, Germany**
Jessica Hankins	**U.S. Food and Drug Administration**
Rob Hahnraths	**Bayer, Germany,** IT Consultant - QA & Validation Services at Bayer. Co-lead of the GAMP® DACH Audit Trail review working group.
Dr Alice Hellwig	**Microcoat Biotechnologie, Germany**, Director Laboratory Services.
Dr Ulrike Herbrand	**Charles River Laboratories, Germany,** Scientific Supervisor Bioassay R&D.
Dr Sunhee Hong	**Charles River Laboratories, USA,** Microbial Solutions R&D Senior Staff Scientist.
Dr Hiltrud Horn	**Horn Pharmaceutical Consulting, Germany** Managing director of HORN PHARMACEUTICAL CONSULTING with focus on CMC, GMP and Regulatory Affairs (EU and US).
Dr Gerd Jilge	**Boehringer Ingelheim Pharma, Germany,** Quality Control. Member of the EDQM expert group 11 and Board Member of the ECA QC Group.
Dr Gerhard Karg	**B.U.G.S, Germany,** Managing Director.
Yutaka Kikuchi	**National Institute of Health Sciences (NIHS), Japan**
Tejs Kyhl	**ALK-Abelló, Denmark** Senior Chemist, Laboratory Automation Development.
Kyrillos Kyriosoglou	**Roche Diagnostics, Germany,** Chemical Engineer.
Aurore de Lavareille	**Celyad, Belgium,** QC Lab Supervisor.
Marine Marius	**Sanofi Pasteur, France,** Scientist in Analytical R&D Microbiology.
Dr Michael J. Miller	**Microbiology Consultants, USA,** Global expert in rapid methods, validation and pharmaceutical microbiology.
Dr Danilo Neri	**PQE, Italy,** Validation Project Manager with expertise on Computer System Validation.
Hans Noordergraaf	**Abbott Biologicals, The Netherlands,** Global Microbiological Expert.
Kai Nesemann	**Sartorius Lab Instruments, Germany,** Global Product Manager DNA-based rapid QC-testing.

Dr Micha Nübling	**Paul-Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines,** Section Head Molecular Virology.
Dr Lucile Plourde Owobi	**Sanofi Pasteur, France,** Senior Scientist, Microbiology Global Analytical Science.
Dr Frank Panofen	**Particle Measuring Systems, Germany,** Product Line Manager Sterility Assurance & Microbiology.
Dr Jörg Peplies	**Ribicon, Germany**, Microbial quality control, computer validation.
Dr Jan Erik Rau	**Lonza, Switzerland,** Head of QC Microbiology.
Christophe Riedel	**Claranor, France,** Business Management.
Dr Ruth Röder	**Microcoat Biotechnologie, Germany**, Project Manager Endotoxin Services.
Prof. Dr. Renate Rosengarten	**University of Veterinary Medicine, Vienna,** Professor and Chair of Bacterioloy and Hygiene.
Margarita Sabater	**Dako Denmark, an Agilent Technologies Company,** Manager Compliance Support at Dako. Board Member of the ECA QC Group.
Dr Frank Sielaff	**Regional Authority Darmstadt, Germany,** GMP inspector with focus on Inspection of drug manufacturers and laboratories in Germany and countries outside of the EU.
Shabnam Solati	**MAT BioTech, The Netherlands,** Co-founder and Lead scientist.
Dr Ingo Spreitzer	**Paul-Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines** Deputy Head of Section 1/3, "Microbial Safety and Parasitology".
Andreas Steinle	**Roche Diagnostics, Germany,** Manager Digital Solutions in Pharma Technical Development Europe.
Dr Peter Steinhardt	**Roche Diagnostics, Germany**, International Alliance Manager, Business Development Pharma & Biotech, EMEA LATAM.
Martin Tabak	**Xendo, The Netherlands,** Consultant.
Klemens Weitenthaler	**VelaLabs, Austria**, Technical Expert.
Kevin Williams	**BioMerieux, USA**
Veronika Wills	**Associates of Cape Cod, USA,** Assistant Manager of Technical Services.
Dr Friedrich von Wintzingerode	**Roche Diagnostics, Germany,** Senior Manager Microbiology, Head of Roche/Genentech global Endotoxin Expert Group and Roche/Genentech global SME on microbial product contaminations.
Samuel Zürcher	**Certus Molecular Diagnostics, Switzerland,** CEO und Co-Founder.

Pre-Conference Workshop
19 November 2018

Supported by

1st International Mycoplasma qPCR Testing User Day

Microbiology

Rapid Mycoplasma Testing - A revolution for Quality Control?
➲ Prof. Dr. Renate Rosengarten, University of Veterinary Medicine Vienna

qPCR Mycoplasma Testing at Roche Pharma - method development, validation, and global roll-out
➲ Dr Alexander Bartes, Roche Diagnostics

External quality assessment of Mycoplasma NATs: regulatory implications
➲ Dr Micha Nübling, Paul-Ehrlich-Institut

Case Study - Implementation of MycoTOOL as a Release Test
➲ Damian Derincovsky, Novartis

Case Study - Approval of MycoTool Roche qPCR assay by FDA, FAMHP and MHRA, accelerating QC release of an autologous cell therapeutic product
➲ Aurore de Lavareille, Celyad

Parallele Round table discussions

Table 1 - MycoTOOL Q&A Session and experience exchange with the developer of the method (Roche Pharma)
Dr Sven Deutschmann and Dr Alexander Bartes, Roche Diagnostics

Table 2 - Rapid Mycoplasma Testing for ATMPs
Jessika Wynendaele and Kim Baert, Anacura
Aurore de Lavareille, Celyad

Table 3 - Implement MycoTOOL on non-validated instrumentation (e.g. other PCR cycler)
Dr Manuela Natoli, Cancer Research UK
Dr Giusy Canino, Roche Diagnostics

Moderation: Dr Peter Steinhardt, Roche Diagnostics

Booking combinations: Combine your booking of the pre-conference with the congress on 20./21.11.2018. Attend the conference *"Rapid Microbiological Methods and Mycoplasma Testing"* on the first congress day or any other conference you are interested in.

The Conferences
20 November 2018

Key Note Presentation at the Plenum
Alternative Microbiological Methods: AstraZeneca's, Johnson&Johnson's, MSD's and Roche's Global Implementation Roadmap

Miriam Guest, AstraZeneca / Philip Breugelmann, JnJ / Marja Claasen, MSD /
Dr. Sven M. Deutschmann, Roche

ECA – Pest Control - from classic trap to digital control

Microbiology

Regulatory Expectation
➲ Dr Rainer Gnibl, Government of Upper Bavaria

Pest Elimination – Outside to inside
➲ Petra Barth, formerly AbbVie

Possibilities and Limits of Monitoring Systems
➲ Gerhard Karg, B.U.G.S

The Pest Management Standard in Pharma - Non-Toxic, zero tolerance and IoT Solutions
➲ Tina Grauwet, SGS

GxP compliant Pest Control in Pharmaceutical Laboratories
➲ Martin Tabak, Xendo b.v.

Case Study: Pest Control Strategy for a New Laboratory Building
➲ Dr Jürgen Balles, Labor LS

Pest Control Strategies for Phytopharmaceutical Manufacturing
➲ Dr Cornelia Bodinet, Schaper & Brümmer

Picture: Labor LS

ECA - Computerised Systems in Analytical Laboratories

Analytics

Regulatory Requirements
➲ Dr Frank Sielaff, GMP Inspector/Germany

The Real Problem - Integration of Existing Instruments to Lab Systems
➲ Andreas Steinle, Roche Diagnostics

Case Study: Paperless Laboratory
➲ Florian Göhner, Vetter Pharma Fertigung

Data Integrity for "Dummies" OR Practical Data Integrity
➲ Rob Hahnraths, Bayer

Audit Trail Review
➲ Tejs Kyhl, ALK

Ensuring Data Integrity throughout the Supply Chain
➲ Dr Danilo Neri, PQE

Integrating Devices and Systems in QC (and Production) to enable Data Driven Decisions
➲ Sinead Cowman, Lonza

Picture: Charles River Laboratories

ECA - Analytical Procedure Lifecycle Management
*** including Launch of the new ECA APLM Guidance**

Analytics

Overview of the new APLM Guideline
➲ Dr Christopher Burgess, Chairman of the ECA AQCG Board

Stage 1: Procedure Design and Development
➲ Margarita Sabater, ECA AQCG Board

Stage 2: Procedure Performance Qualification (PPQ)
➲ Dr Gerd Jilge, ECA AQCG Board

Stage 3: Procedure Performance Verification
➲ Silviya Dimitrova, ECA AQCG Board

APLM Questionnaire
➲ Dr Christopher Burgess, Chairman of the ECA AQCG Board

Workshop Critique of a SWOT Analysis of the APLM
➲ Dr Christopher Burgess, Chairman of the ECA AQCG Board

ICH Concept Paper for Revision of Q2(R2) & Q14
➲ Dr Christopher Burgess, Chairman of the ECA AQCG Board

Interactive discussion of the ICH implications and Questions
➲ All members of the ECA AQCG Board

Every participant will receive Version 01 of the **Laboratory Management Guidance Analytical Procedure Lifecycle Management** developed by the ECA Analytical Quality Control Group.

ECA – Endotoxin and Pyrogen Testing (Day 1)

Microbiology

Current US Regulation and FDAs Thinking
➲ Jessica Hankins, U.S. Food and Drug Administration

PDA LER Technical Report Scope, Overview, Impact on Industry
➲ Dr Friedrich von Wintzingerode, Roche Diagnostics

The Evolution of Endotoxin Test
➲ Kevin Williams, bioMerieux

LER – An alternative Explanation
➲ John Dubczak, Charles River Laboratories

Pyrogenicity of Food Supplements - Comperative Study of MAT, BET and rFC
➲ Stefan Gärtner, Labor LS

From First Evaluation to a Representative Endotoxin Test: a Story about Masking
➲ Dr Jan Erik Rau, Lonza

An approach to LER (Low Endotoxin Recovery) & Update of EP chapter 5.1.10
➲ Hans Noordergraaf, Abbott Biologicals

Evaluation of new solutions for endotoxin testing for water samples
➲ Marine Marius, Sanofi Pasteur

(1 -> 3)-ß-D-Glucan: A biological response modifier found as a contaminant in pharmaceuticals
➲ Veronika Wills, ACC

The Conferences
20. November 2018

ECA – Rapid Microbiological Methods and Mycoplasma Testing

Microbiology

Microbial test automation to support plate incubation and enumeration
➲ Dr Lucile Plourde Owobi, Sanofi Pasteur

Present and Future of Molecular Microbial Identification – Bridging of Scientific Progress and Practical Application in Regulated Environments
➲ Dr Jörg Peplies, Ribocon

Bringing Innovation into quality control: How a novel Isothermal mycoplasma assay changes the race
➲ Samuel Zürcher, Certus Molecular Diagnostics

Rapid detection of bacteria in ATMP prior treatment - validation of a qPCR-based test
➲ Kai Nesemann, Sartorius

Understanding the Revised Ph. Eur. Chapter 5.1.6 and how it compares with USP 1223, PDA Technical Report 33 and Industry Best Practices
➲ Dr Michael Miller, Microbiology Consultants

Strategies for Rapid Sterility Testing of Gene and Cell Therapy Products
➲ Dr Michael Miller, Microbiology Consultants

Modern alternative viable air monitoring in light of the new Annex 1 draft
➲ Dr Frank Panofen, Particle Measuring Systems

Using an alternative gene sequence for species-level identification for members of the Burkholderia cepacia complex (Bcc).
➲ Dr Sunhee Hong, Charles River Laboratories

Pulse Light Decontamination - Robotic Tub Decontaminating System
➲ Christophe Riedel, Claranor
➲ Mario Fusi, Steriline

Picture: Vela Labs

The Conferences
21 November 2018

Key Note Presentation at the Plenum
ECA Analytical Quality Control Group: Aims, Achievements and Activities

Dr Christopher Burgess, Chairman of the ECA QC Group

ECA – Analytical Challenges for Biological Drug Substances and Products Objective

Bioanalytics

The Revised FDA Guidance on the validation of analytical methods
➲ Dr Markus Fido, VelaLabs

What do we need of information from a potency assay?
➲ Dr Jan Amstrup, Novo Nordisk

Challenges in Bioactivity Determination
➲ Dr. Ulrike Herbrand, CRL

The interdependence of Bioassays and Structural characterisation
➲ Klemens Weitenthaler, VelaLabs

Single Molecular Detection – A new technology
➲ Dr Alice Hellwig, Microcoat Biotechnologie

Getting Host Cell DNA analysis up to speed with an automated System
➲ Kyrillos Kyriosoglou, Roche Diagnostics

Development and Validation of an Excel workbook for automated sample information management in the analytical lab
➲ Dr Michael Haberl, Microcoat Biotechnologie

ECA – Endotoxin and Pyrogen Testing (Day 2)

Microbiology

Requirements of JP
➲ Yutaka Kikuchi, National Institute of Health Sciences

LPS Structure
➲ Martine Caroff, LPS Bioscience

Biophysical interpretation of a systematic comparison of MAT and BET for LER understanding
➲ Wilmar Correa, Research Center Borstel

Pyrogen and Endotoxin Testing – Where do we go?
➲ Dr Ingo Spreitzer, Paul-Ehrlich-Institut

Monocyte Activation Test for predicting pyrogenic content in vaccines without animal models
➲ Dr Barabara Capecchi, GSK

Challenges in applying the Monocyte Activation Test for routine testing in the QC environment
➲ Dr Ruth Röder, Microcoat

Pyrogen detection with the cryopreserved PBMC-based MAT Cell Set: performance, study examples and challenges
➲ Dr Eelo Gitz, Sanquin

Pyrogen detection with the MM6 cell-line: implementation as a routine test
➲ Mathilde Arnault/Dr Anja Fritsch, Merck/Confarma

Healthy human immune cells as pyrogen detection source and advancement of drug release testing
➲ Shabnam Solati, MAT Biotech

Picture: Charles River Laboratories

ECA – QC Compliance Trends in Analytical Laboratories

Analytics

Current Experiences from GMP Inspections in QC Labs
➲ Dr Frank Sielaff, GMP Inspector/Germany

Cleaning Validation of Analytical Equipment
➲ Dieter Brillert, Wiewelhove

cGMP Compliance Trends in Analytical Labs - addressing the impact of the Brexit for Pharma
➲ Dr Hiltrud Horn, Horn Pharmaceutical Consulting

Defining and Managing Raw Data
➲ Tejs Kyhl, ALK-Abelló

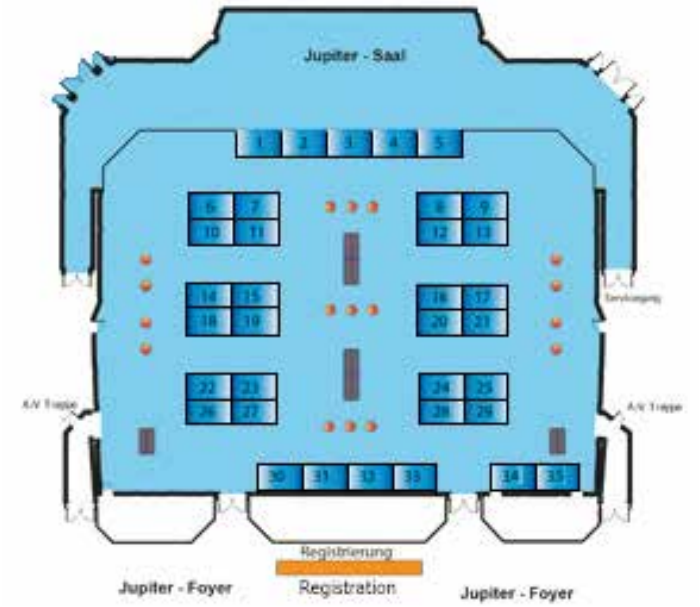
Current Trends at FDA and future of FDA Inspections (MRA)
➲ Dr Hiltrud Horn

Training in QC
➲ Ulla Bondegaard, Novo Nordisk

The Exhibition

Is your company specialised in products and services for pharma laboratories?

As an exhibitor in the PharmaLab exhibition you can take advantage of the unique opportunity to directly address users and decision makers in the areas analytics, bioanalytics, from microbiological laboratories, Quality Assurance and Quality Control. In addition to high-level discussions during the Congress you can also get in touch with Congress delegates with speakers during the Social Event.



The **charges per stand are 3.980,- Euro** plus VAT. The following services are included:

- 2 one day tickets per 590,- Euro[1]
- Reduced one day tickets for inviting your customers
- Participation for the person mentioned on the form below is free of charge
- Lunch and refreshments during the conferences
- Participation in the Social Event
- Maximum size of the stand: app. 3 x 2 m
- 1 table, 2 chairs and power
- On-site support

If you want to be part of this industry meeting you should register your stand soon.

As an exhibitor you can take advantage of various marketing materials for promoting your presence. These include

Materials for your Marketing

- online exhibition banner – for your website and as signature in your e-mails.
- exhibition stickers – for your business mail
- an ad in the GMP Journal (subject to extra charges) – get directly in touch with your target group

You will find more detailed information on these materials on the Congress website at www.pharmalab-congress.com.

Sponsoring

Moreover, take advantage of the sponsoring opportunities to make Congress delegates aware of your company. In addition to sponsoring coffe breaks or lunches on the 1st and 2nd Congress day there are plenty of other sponsor possibilities. You will find the details on the website.

The Contacts

Do you have any questions with regard to the exhibition? Then please contact:
Ronny Strohwald, (Organisation), Tel. +49 (0) 6221/84 44-51,
E-Mail: strohwald@concept-heidelberg.de.

[1] *One day tickets will be mailed. Guests will need to register on the PharmaLab website at www.pharmalab-congress.com. Please note that one day tickets are not for exhibitor staff.*

Registration for the Exhibition – PharmaLab 2018

Registration for a stand at the PharmaLab 2018 on 20/21 November 2018 in Düsseldorf/Neuss.
For the registration of your stand you can also alternatively use the online registration form, which you will find on the website at **www.pharmalab-congress.com**. The charges for a stand are 3.980,- Euro plus VAT.
(Please note that exhibitors will be responsible for all charges for building and taking down of stand as well as for all materials related to the presentation.)

☐ **I want to register a stand with the stand number below.**
(Please note that for cancellation after 31 July 2018 the full registration fee of 3.980,- Euro will be charged. In addition, the General Terms and Conditions for Fairs/Exhibitions as available on the PharmaLab website do apply.)

The exhibitor plan on the website at www. pharmalab-congress.com is updated every day. Please take a look at this plan to see what spaces are still open and to pick your stand number which you then fill in here:

Preferred Stand Number: _____ or alternatively _____

Registration / Reservation – Company Information / Invoice Address:

Company	
Contact	
Department	
Phone / Fax	
E-Mail	
Contact on site – this person is also free to attend all conferences (registration as delegate included):	
First & Last Name	
Department	
Street, ZIP & City	
Phone / E-Mail	
Invoice Address	
Participation in Social Event on 20 November 2018: Yes ☐ No ☐	

Additional Stand Personnel:
For additional stand personnel a flat rate of € 300, - will be charged per person. Please register additional personnel together with your registration as exhibitor. The participation of conferences is not included.

	Stand Personnel – Person 1:	Stand Personnel – Person 2:
Company		
First & Last Name		
Street, ZIP & City		
Phone / E-Mail		
Invoice Address		
Participation in Social Event on 20 November 2018:	Yes ☐ No ☐	Yes ☐ No ☐

Conference Selection for Congress Delegate (not for Stand Personnel):
PharmaLab 2018 delegates are free to attend the conferences they are interested in. To set up the conference rooms, though, we would appreciate it if you let us know what conference you are specifically interested in – **please mark your choice per day below**.

19 November 2018: ☐ ECA - 1st International Mycoplasma qPCR Testing User Day (including Networking Dinner) € 249,- plus VAT

20 November	☐ ECA – Analytical Procedure Lifecycle Management	**21 November**	☐ ECA – Analytical Challenges for Biological Drug Substances and Products
	☐ ECA – Computerised Systems in Analytical Laboratories		☐ ECA - QC Compliance Trends in Analytical Laboratories
	☐ ECA – Pest Control		☐ ECA – Endotoxin and Pyrogen Testing (Day 2)
	☐ ECA – Endotoxin and Pyrogen Testing (Day 1)		
	☐ ECA – Rapid Microbiological Methods and Mycoplasma Testing		

Room Reservation:
Direct room reservation by reservation form! Reservations/bookings cannot be made through Concept Heidelberg. Receipt with confirmation/invoice.
CONCEPT HEIDELBERG has reserved a limited number of rooms in the Swissôtel Düsseldorf/Neuss. You can make your room reservation directly with the reservation form you will receive together with the registration confirmation. We recommend to register early.

Court of jurisdiction is Heidelberg, German law is applicable. In addition, the General Terms and Conditions for Fairs/Exhibitions as available on the PharmaLab website at www.pharmalab-congress.com do apply.

City and Date _____ Signature _____

Please complete the form and return to CONCEPT HEIDELBERG, Fax +49 (0) 6221 84 44 34.

Registration Form:
CONCEPT HEIDELBERG
Rischerstraße 8
69123 Heidelberg, Germany

Registration Form:
+49 (0) 6221 84 44 34

E-Mail:
info@concept-heidelberg.de

Internet:
www.pharmalab-congress.com
www.pharmalab-kongress.de

Registration Options PharmaLab 2018

I want to take part in:

- ☐ **PharmaLab Pre-Conference "1st International Mycoplasma qPCR Testing User Day" (19.11.2018 including Networking Dinner) - € 249,- plus VAT**
- ☐ **PharmaLab Conferences on 20.11.2018 – € 690,- plus VAT**
- ☐ **PharmaLab Conferences on 21.11.2018 – € 690,- plus VAT**

With a one day ticket/two days ticket for the PharmaLab Conferences (20.11/21.11.2018)you can attend any conference offered that day/both days. It includes participation in any conference on that day/on both days and the visit of the exhibition. In addition, it comprises lunch and beverages during the conferences and in breaks (on one or both days) as well as the social event on the evening of the first congress day. Please mark if you would like to attend the Social Event.

To be able to prepare the conference rooms, we would appreciate it if you marked the conference you are interested in. Please also mark the day you plan on attending the Congress. **Please mark only one conference per day.**

☐ I would like to attend on **day 1 (20 November 2018)** and I'm primarily interested in the conference:

- ☐ ECA – Pest Control
- ☐ ECA – Computerised Systems in Analytical Laboratories
- ☐ ECA – Analytical Procedure Lifecycle Management
- ☐ ECA – Endotoxin and Pyrogen Testing (Day 1)
- ☐ ECA – Rapid Microbiological Methods and Mycoplasma Testing

☐ I would also like to take part in the Social Event on the evening of 20 November.

☐ I would like to attend on **day 2 (21 November 2018)** and I'm primarily interested in the conference:

- ☐ ECA – Analytical Challenges for Biological Drug Substances and Products
- ☐ ECA – QC Compliance Trends in Analytical Laboratories
- ☐ ECA – Endotoxin and Pyrogen Testing (Day 2)

PLEASE NOTE:

- There will be no 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.
- 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 will also receive the presentations on a USB stick at the registration center.

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

☐ Mr ☐ Ms ☐ Dr

First name, Surname

Company

Department

Important: Please indicate your company's VAT ID Number P.O. Number (if applicable)

Street/P.O. Box

City Zip Code

Country

Phone/Fax

E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34
D-69007 Heidelberg
GERMANY

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid.

CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. CONCEPT HEIDELBERG will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. CONCEPT HEIDELBERG will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

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