

# PharmaLab 2018

**Analytics, Bioanalytics and Microbiology**

**– Congress & Exhibition –**

**Crowne Plaza Düsseldorf/Neuss**

**20/21 November 2018**

[www.pharmalab-congress.com](http://www.pharmalab-congress.com)

Exhibitor Information in the back of the programme

## The Conferences

### 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)

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

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EUROPEAN PHARMACEUTICAL REVIEW

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## 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	
	<b>Key Note 20 November</b> Alternative Microbiological Methods: AstraZeneca's, GSK's, Johnson&Johnson's, MSD's and Roche's Global Implementation Roadmap <i>Miriam Guest, AstraZeneca / Philip Breugelmann, JnJ / Dr Sven M. Deutschmann, Roche</i>
	<b>Key Note 21 November</b> ECA Analytical Quality Control Group: Aims, Achievements and Activities <i>Dr Christopher Burgess, Chairman of the ECA Analytical Quality Control Group</i>
<b>Pre-Conference Workshop (fully booked up)</b>	
19 November 2018	
ECA - 1st International Mycoplasma qPCR Testing User Day	
<b>Conferences</b>	<b>One day ticket 690,- EUR</b>
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	
<b>Exhibition (20 and 21 November 2018)</b>	

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). 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  
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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 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](http://www.eurobiotechnews.eu).



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](http://www.European-PharmaceuticalReview.com) for further information.

## Speakers (as of November 2018)

Dr Jan Amstrup	Novo Nordisk, Denmark, Principal Scientist.
Mathilde Arnault	Merk, France, Research Scientist - BioMonitoring R&D.
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.
Larissa Ebeling	EbeTech North America, Inc / Steriline US, Sales and Marketing.
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).
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.
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 Thomas Meindl	Labor LS, Germany, Division Manager of various departments (Assays, Endotoxins, R&D, Molecular biology, Disinfectant testing and computerized systems).
Dr Michael J. Miller	Microbiology Consultants, USA, Global expert in rapid methods, validation and pharmaceutical microbiology.
Dr Sonja Molinaro	Microcoat Biotechnologie, Germany, General Manager.
Dr Danilo Neri	PQE, Italy, Validation Project Manager with expertise on Computer System Validation.
Hans Noordergraaf	Abbott Biologicals, The Netherlands, Global Microbiological Expert.
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 Karl Pflanz	Sartorius Lab Instruments, Germany. Director R&D and Business Area Coordinator for Lab Filtration, Purification and Microbiology.
Dr Jan Erik Rau	Lonza, Switzerland, Head of QC Microbiology.
Nicola Reid	Charles River Laboratories, France; Senior Product Manager.
Christophe Riedel	Claranor, France, Business Management.
Dr Ruth Röder	Microcoat Biotechnology, Germany, Project Manager Endotoxin Services.
Prof. Dr. Renate Rosengarten	University of Veterinary Medicine, Vienna, Professor and Chair of Bacteriology 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	CTL-MAT, USA, Co-Founder and CEO.
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 cyclers)

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, GSK's, Johnson&Johnson's, MSD's and Roche's Global Implementation Roadmap

Miriam Guest, AstraZeneca / Philip Breugelmann, Jnj / Dr. Sven M. Deutschmann, Roche



## ECA - Pest Control - from classic trap to digital control

Microbiology

### Regulatory Expectation

➔ Dr Rainer Gnihl, 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 Thomas Meindl, Labor LS

### Pest Control Strategies for Phytopharmaceutical Manufacturing

➔ Dr Cornelia Bodinet, Schaper & Brümmer



Picture: Labor LS

**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 Hahnraaths, 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

**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)**

**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

**Data-based decision-making in Endotoxin Testing**

➤ Nicola Reid, Charles River Laboratories

**Pyrogenicity of Food Supplements - Comparative 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)-β-D-Glucan: A biological response modifier found as a contaminant in pharmaceuticals**

➤ Veronika Wills, ACC

**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**

➔ Dr Karl Pflanz, 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

➔ Larissa Ebeling, EbeTech



Picture: Vela Labs

**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**

**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 Weienthaler, 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 Sonja Molinaro, Microcoat Biotechnologie



**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 Barbara 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, CTL-MAT



Picture: Charles River Laboratories

ECA – QC Compliance Trends in Analytical Laboratories

**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

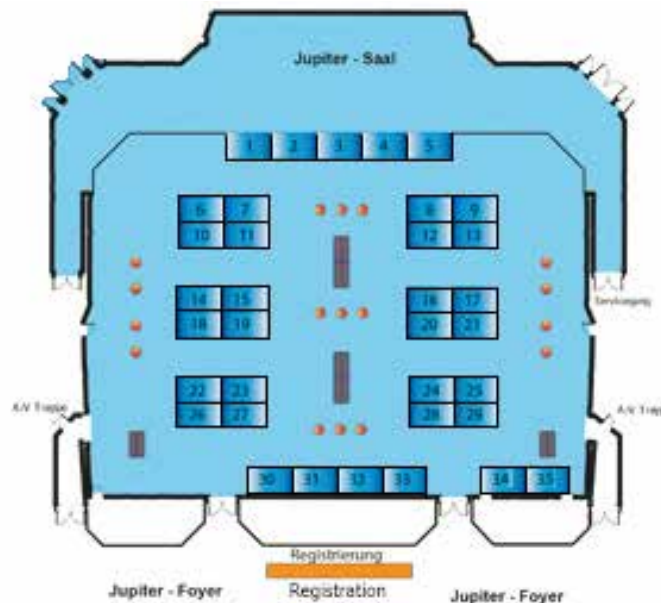
**Training in QC**

➤ 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<sup>1</sup>
- 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](http://www.pharmalab-congress.com).

### Sponsoring

Moreover, take advantage of the sponsoring opportunities to make Congress delegates aware of your company. In addition to sponsoring coffee 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](mailto:strohwald@concept-heidelberg.de).

<sup>1</sup> One day tickets will be mailed. Guests will need to register on the PharmaLab website at [www.pharmalab-congress.com](http://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](http://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](http://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.**

<b>20 November</b>	<input type="checkbox"/> ECA – Analytical Procedure Lifecycle Management	<b>21 November</b>	<input type="checkbox"/> ECA – Analytical Challenges for Biological Drug Substances and Products
	<input type="checkbox"/> ECA – Computerised Systems in Analytical Laboratories		<input type="checkbox"/> ECA - QC Compliance Trends in Analytical Laboratories
	<input type="checkbox"/> ECA – Pest Control		<input type="checkbox"/> ECA – Endotoxin and Pyrogen Testing (Day 2)
	<input type="checkbox"/> ECA – Endotoxin and Pyrogen Testing (Day 1)		
	<input type="checkbox"/> 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](http://www.pharmalab-congress.com) do apply.

City and Date

Signature

# 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 (fully booked up)

- 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:

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

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)

### 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.