

Exhibtor Information in the back of the programme

### The Conferences

### 11 November 2019

■ Pre-Conference Workshop: ECA - 2nd International Mycoplasma qPCR Testing User Day

### 12 November 2019

- ECA Rapid Microbiological Methods
- ECA Analytical Procedure Lifecycle Management Revisions to ICH Q2 & the proposed Q14 (Day 1)
- ECA Endotoxin and Pyrogen Testing (Day 1)
- ECA Bioanalytics and Bioassays Challenges for Biological Drug Substances and Products

### 13 November 2019

- ECA Microbiological Real Time Counting and Testing
- ECA Analytical Procedure Lifecycle Management Revisions to ICH Q2 & the proposed Q14 (Day 2)
- ECA Endotoxin and Pyrogen Testing (Day 2)
- ECA Testing and Analytics of Cells, Tissues and ATMPs

CONCEPT HEIDELBERG

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

Media Partner





Pharmaceutical Quality Training. Conferences. Services.

#### The Congress Objective

From 11 to 13 November 2019 the PharmaLab Congress will take place in Düsseldorf/Neuss for the seventh time. This Congress addressing staff and executives in all lab areas of the pharmaceutical industry will be comprised of one pre-conference workshop, eight international and two German language conference 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 2019 Overview**

### **1** Key Note 12 November

New ICH Q14 and ICH Q2 Revision – an industry view

Dr Joachim Ermer, Sanofi-Aventis Deutschland, Head of QC Lifecycle Management Frankfurt Chemistry

### **1** Key Note 13 November

Laboratory Services - from Outsourcing to a strategic partnership Dr Jürgen Balles, Dr Thomas Meindl and Ingo Grimm, Labor LS

One day ticket 690,- EUR Early Bird Rebate: until 31 August 2018 only 590,- EUR

	TRACK 1 QC Analytics	TRACK 2 QC Endotoxin & Pyrogen Testing	TRACK 3 QC Microbiology	TRACK 4 QC Bioanalytic / Biotech
Day 1 - 12 Nov 2019	Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14	Alternative Methods (MAT, recombinant Factors)	Rapid Microbiological Methods	Challenges in Bioanalytics and Bioassays
Day 2 - 13 Nov 2019	Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14	Routine Testing and LER/Masking	Microbiological Real Time Counting and Testing	Testing and Analytics of Cells, Tissues and ATMPs

#### Exhibition (12 and 13 November 2019)

### Pre-Conference Workshop on 11 November 2019:

The day before the congress the pre-conference event "2nd International Mycoplasma qPCR Testing User Day" will take place. Ticket 490,- EUR - Early Bird Rebate: until 31 August 2019 only 440,- EUR

### 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 (12 November/13 November 2019) either only on day 1 or only on day 2 or on both days. The charges for the one day tickets are  $\in$  690,- (until 31 August 2019 only  $\in$  590,-) plus VAT, for the two days ticket  $\in$  1.380,- (until 31 August 2019 only  $\in$  1.180,-) 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 11 November 2019 for  $\in$  490,- (until 31 August 2019 only  $\in$  440,-) 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 2019

- 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 12 November 2019, 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 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 \*ECA\* \*ECA\* \*\*\* D-69007 Heidelberg Telefon+49 (0) 62 21/84 44-0

Telefon+49 (0) 62 21/84 44-0 Telefax +49 (0) 62 21/84 44 34 E-Mail: info@concept-heidelberg.de, www.concept-heidelberg.com

#### **The Contacts**

### For questions regarding content:

Axel H. Schroeder (Operations Director), Tel. +49 (0) 6221/84 44 10,

E-Mail: schroeder@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.

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.EuropeanPharmaceuticalReview.com for further information.

Speakers (as of May 2019)

**Dr Alexander Bartes** Roche Diagnostics, Germany, Senior Quality Control Manager.

**Ulla Bondegaard Novo Nordisk, Denmark,** Currently responsible for maintaining cross-organisational (and cross-country)

laboratory processes.

Phil Borman GSK, UK, Product Development.

Chiara Celli Merck, Italy, QA Trainer.

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 Jörg Degen Eurofins BioPharma Product Testing, Germany, Head of Microbiology.

Dr Sven M. Deutschmann Roche Diagnostics, Germany, Head of Global ASAT "Adventitious Agents Testing & Alternative Microbiologica.

Chairman of the Advisory Board of the ECA "Pharmaceutical Microbiology Interest Group", Member of PDA Task

orces.

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.

Thomas Fechner Agilent Technologies, Germany, Principal Scientist.

**Dr Anja Fritsch**Confarma, France, Responsible for cell based bioassays (development and routine).

**Barbara Gerten** Merck, Germany, Chairwoman DIN Working Group Microbiological Food Testing incl.

Rapid Methods.

Dr Eelo GitzSanquin Reagents , The Netherlands, Project manager product development.Dr Qing HeChinese National Institutes for Food and Drug Control, Pharmacology Division.

Dr Jessica Hankins U.S. Food and Drug Administration

Dr Mizumura Hikaru Seikagaku, Japan

Christiane Höfner Labor LS, Germany, Senior Expert Microbiological Testing..

Dr Gerd Jilge Boehringer Ingelheim, Germany, Quality Control. Member of the EDQM expert group 11 and Board Member of

the ECA QC Group.

**Dr David Jones** Rapid Micro Biosystems, USA, Technical Services Director.

**Dr Ilona Kalaszczynska Medical University of Warsaw, Poland,** Scientist at University Warsaw and QC Manager BMCT.

Jan-Oliver Karo Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines, Division Microbial Safety.

Quality assessor and national expert advisor for the microbial safety of ATMPs. Member of the "Cell Therapy

Products" Working Party of the German Pharmacopoeia Commissión.

**Dr Prasanna Khot** Charles River Laboratories, USA, Senior Research Scientist Microbial Solutions.

**Luka Kosec** JAZMP - Slovenian medicinal Agency, Quality Assessor.

**Dr Philip Kuhlmann** Reading Scientific Services Limited (RSSL), UK, Technical Specialist, Bio-Molecular Analysis

Laboratory

Annette Kunz CSL Behring, Switzerland, Manager Monitoring.

Dr Claude Lemarié Center for Cell Therapy Marseille, France, QC Management.

Marine Marius Sanofi Pasteur, France, Scientist in Analytical R&D Microbiology.

Bob McDowall Limited, UK, Director.

Dr Michael J. Miller Microbiology Consultants, USA, Global expert in rapid methods, validation and pharmaceutical microbiology.

Dr Félix A. Montero Julian bioMerieux, France, Scientific Director.

Alexander Negwer Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines,

Scientist Section 1/3, "Microbial Safety and Parasitology".

Kai Nesemann Sartorius Labs Instrument, Germany, Global Product Manager DNA-based rapid QC-testing.

**Dr Jelena Novakovic** Galenika, Serbia, Senior Expert Associate.

**Dr Farnaz Nowroozi** Genentech, USA, Scientist and Manager - Global Analytical Science and Technology.

Kham Nguyen Rapid Micro Biosystems, USA, QC Scientist.

Diarmaid O'Riordan Pfizer, Ireland, QC Microbiologist.

**Dr Claudia Papewalis** Valicare, Germany, Senior GMP Consultant.

**Diana Patzelt** Sartorius Stedim Biotech, Germany, Scientist - Applications for Molecular Biology.

**Katrin Pauls** Lonza, Germany, Market Development and Scientific Affairs Manager.

Joseph PierquinRedberry, France, Chief Technical Officer.Dr Jan Erik RauLonza, Switzerland, Head of QC Microbiology.

**Dr Johannes Reich Microcoat Biotechnologie, Germany,** General Manager.

Nicola Reid Charles River Laboratories, UK, Senior Product Manager.

Dr Antonio Rodríguez Acosta Andalusian Initiative for Advanced Therapies, Quality Manager and Deputy Qualified Person at Cell

Manufacturing Unit (Regional University Hospital, Málaga. Spain).

**Dr Ruth Röder** Microcoat Biotechnologie, Germany, Project Manager Endotoxin Services.

**Dr Sigrid Roosendaal Quality RA, The Netherlands, Senior Consultant.** 

Dr David Roesti Novartis Pharma Stein, Switzerland, Technical Steward Microbiology, Manufacturing Science & Technology.

Markus Roucka VelaLabs – A Tentamus Company, Austria, Lab Head and Business Development.

Margarita Sabater Dako Denmark, an Agilent Technologies Company, Manager Compliance Support at Dako.

Board Member of the ECA QC Group.

**Dr. Gerold Schwarz**Bruker Deltronics, Germany, Manager Application Support.

Prof. Dr. Dr. Hartwig Schulz Medicinal and Aroma Plants, Germany, Consulting and Project Management. Used to work for the Julius-Kühn

Institut.

Dr Milanka Setina National Control Laboratory Medicines and Medical Devices Agency of Serbia, Scientist.

Dr Ingo Spreitzer Paul-Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines

Deputy Head of Section 1/3, "Microbial Safety and Parasitology".

**Dr Peter Steinhardt**Roche Diagnostics, Germany, International Alliance Manager, Business Development Pharma & Biotech, EMEA

LATAM.

Andrej Steyer University of Ljubljana, Slovenia, Institute of Microbiology and Immunology Faculty of Medicine.

**Jonas van den Berg** Roche, Germany, Validation of the Celsis-based Alternative Sterility Test.

Klemens Weitenthaler VelaLabs – A Tentamus Company, Austria, Technical Expert.

**Kevin Williams** BioMerieux, USA, Endotoxin Expert.

Veronika Wills Associates of Cape Cod, USA, Manager technical Services.

### Pre-Conference Workshop 11 November 2019

### 2nd International Mycoplasma qPCR Testing User Day

Pitfalls and Issues on Mycoplasma Testing according to Pharmacopoeial Requirements

⇒ Jan-Oliver Karo, Paul-Ehrlich Institut

Rapid Mycoplasma Detection – How Stochastics Can Help

Dr Philip Kuhlman, RSSL

Automatization of Mycoplasma detection using a new fast and easy to use molecular method

Dr Félix A. Montero Julian, bioMerieux

Comparability Study of a Real-time PCR-based Mycoplasma detection kit with the culture method according to EP 2.6.7

⇒ Diana Patzelt, Sartorius Stedim Biotech

Mycoplasma detection system and its verification

→ Andrej Steyer, University of Ljubljana

Summary

→ Dr Peter Steinhardt, Roche

Moderation: Dr Peter Steinhardt, Roche

**Booking combinations:** Combine your booking of the pre-conference with the congress on 12 Nov/13 Nov 2019. Attend the conference "Rapid Microbiological Methods" on the first congress day or any other conference you are interested in.

## The Conferences 12 November 2019

# Key Note Presentation at the Plenum New ICH Q14 and ICH Q2 Revision – an industry view

Dr Joachim Ermer, Sanofi-Aventis Deutschland, Head of QC Lifecycle Management Frankfurt Chemistry

### ECA - Rapid Microbiological Methods

TRACK 3

RMM Validation - ECA PMWG /PEI Activities

⇒ Dr Sven M. Deutschmann, Roche

RMM Validation Guide Food - A Look to the Neighbourhood

⇒ Barbara Gerten, Merck

Evaluation and Optimization of MALDI-TOF for Identification of Filamentous Fungi

Dr Gerold Schwarz, Bruker Daltronics

⇒ Dr Prasanna Khot, CRL

Validation of the Celsis-based Alternative Sterility Test

⇒ Jonas van den Berg, Roche

Rapid Micro instruments: secure implementation to LIMS for data security

➡ Kham Nguyen / Dr David Jones, Rapid Micro Biosystems

A Practical Guide on how to demonstrate a significant return of investement when implementing Real-Time RMMs

→ Dr Michael Miller, Microbiology Consultants

**PCR - Rodent Parvo Virus Testing** 

**⊃** Dr Alexander Bartes, Roche

Rapid detection of bacteria and fungi in ATMP prior treatment - Validation of a Real-time PCR-based test

⇒ Kai Nesemann, Sartorius Labs Instruments



## ECA - Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14 (Day 1)

TRACK 1

#### Introduction to ECA AQCG

→ Dr Christopher Burgess, Burgess Analytical Consultancy

#### Overview of ICH revisions & APLM Guideline; Prerequisites and approaches

⇒ Dr Christopher Burgess, Burgess Analytical Consultancy

#### Introduction to ATP & TMU

⇒ Phil Borman, GSK

### Data integrity over the Analytical Procedure Lifecycle

⇒ Dr Bob McDowall, R.D. McDowall Limited

#### Stage 1: Procedure Design & Development

→ Margarita Sabater, Dako Denmark, an Agilent Technologies Company

### Stage 1 in Practice

⇒ Phil Borman, GSK

### **Analytical Control Strategy Workshop**

**⊃** Dr Gerd Jilge, Boehringer Ingelheim

Margarita Sabater, Dako Denmark, an Agilent Technologies Company



### ECA – Endotoxin and Pyrogen Testing (Day 1)

TRACK 2

#### **MAT Task Force**

⇒ Dr Sven Deutschmann, Roche

### Validation of MAT – Regulatory Experiences

⇒ Dr Ingo Spreitzer, Paul-Ehrlich Institut

## Development of the Monocyte Activation Test on vaccines containing inherently pyrogenic components

➡ Stéphanie Richard, Sanofi Pasteur

### Comparison of a Monocyte Activation Test based on fetal bovine serum and on human AB serum

⇒ Dr Eelo Gitz, Sanquin

## Pyrogenicity associated with heat-inactivated microorganisms isolated in our laboratory from actual samples

→ Dr Anja Fritsch, Confarma

### MAT implementation: from validation to use in routine in a GMP QC Lab

→ Chiara Celli, Merck

#### MAT - Ready for GMP Routine?

→ Christiane Höfner, Labor LS

#### The Monocyte Activation Test: Validation & Analysis

➡ Katrin Pauls, Lonza

### Endotoxin, ten misconceptions around detection and controls

Kevin Williams, bioMérieux

## ECA – Bioanalytics and Bioassays - Challenges for Biological Drug Substances and Products

TRACK 4

### Description of analytical procedure and validation, a regulator's view

⇒ Luka Kosec, JAZMP - Slovenian medicinal Agency

### How to overcome some of the challenges when analysing Biological Drug Substances and Products

→ Thomas Fechner, Agilent

### Analytical Quality by Design Through the Lifecycle

⇒ Patrick Jackson, GSK

### State-of-the-Art evaluation of potency bioassays

➡ Klemens Weitenthaler, VelaLabs – A Tentamus Company

### Application of fast and non-destructive analysis techniques in quality and in-process control

⇒ Prof. Dr. Dr. Hartwig Schulz, Medicinal and Aroma Plants (ehem. Julius-Kühn Institut)

### Lectin Array – a novel technology for investigation of pharmaceutical products

→ Markus Roucka, VelaLabs – A Tentamus Company

### Key Note Presentation at the Plenum Laboratory Services - from Outsourcing to a strategic partnership

Dr Jürgen Balles, Dr Thomas Meindl and Ingo Grimm, Labor LS

### ECA – Microbiological Real Time Counting and Testing

TRACK 3

### Different Measurement Methods/Systems - Pros and Cons

⇒ Annette Kunz, CSL

### Mettler System - Implementierung

⇒ Natascha Staub, Mibelle

### **Automated Colony Counting**

- → Dr Jan Erik Rau, Lonza→ t.b.a, Lonza

Evaluation of the Scanstation 100 system for the automated incubation and analysis of pharmaceutical environmental monitoring samples using standard Petri plates

⇒ Diarmaid O'Riordan, Pfizer

### Case Study: Using continuous Real-Time intrinsic Fluorescence Techniques for EM in Isolators

→ Dr Michael Miller, Microbiology Consultants

#### Experiences at Roche - Water/EM?

t.b.a.

#### Monitoring/Trending

Dr David Roesti, Novartis

### New Generation of Solid Phase Cytometry for Rapid Detection of Microbiological Contaminants in Water Samples

⇒ Joseph Pierquin, Redberry



### ECA - Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14 (Day 2)

TRACK 1

### Stage 2: Procedure Performance Qualification; problems and issues?

⇒ Dr Gerd Jilge, Boehringer Ingelheim

### **Approaches to the transfer of Analytical Procedures**

⇒ Ulla Bondegaard, Novo Nordisk

### Stage 3: Procedure Performance Verification

⇒ Silviya Dimitrova, Teva

### **Experiences in the ongoing verification of Analytical Procedures**

→ Ulla Bondegaard, Novo Nordisk

### "What happens with Legacy Products?" Workshop

- → Margarita Sabater, Dako Denmark, an Agilent Technologies Company
- ⇒ Dr Christopher Burgess, Burgess Analytical Consultancy

### ECA – Endotoxin and Pyrogen Testing (Day 2)

TRACK 2

### Current development in Endotoxin and Pyrogen Testing – FDA Point of View

→ Dr Jessica Hankins, U.S. Food and Drug Administration

### Putting Patient Safety First, View from the other side

Dr Milanka Setina, Medicines and Medical Devices Agency of Serbia

### Implementing PDA Technical Report on LER in an analytical control strategy

Dr Farnaz Nowroozi, Genentech

### **Endotoxin and Pyrogen detection of LER Samples**

Alexander Negwer, Paul-Ehrlich Institut

#### **Endotoxins – Requirements of CP**

→ Dr Qing He, Chinese National Institutes for Food and Drug Control

#### **Practical Insights in BET**

Dr Jelena Novakovic, Galenika

#### A Global Perspective for Quantifying All Endotoxins within Pharmaceutical Water Systems

Nicola Reid, CRL

#### **LER - Current Data**

→ Dr Johannes Reich, Microcoat Biotechnologie

### PyroSmart - a chromogenic recombinant reagent for endotoxin testing

- → Dr Mizumura Hikaru, Seikagaku→ Veronika Wills, ACC

### Implementation of rFC for product testing

→ Marine Marius, Sanofi



### ECA – Testing and Analytics of Cells, Tissues and ATMPs

TRACK 4

### Suitability of the test method for the test 'Microbiological Examination of cell-based Preparations' according to EP 2.6.27

⇒ Dr Jörg Degen, Eurofins Product Testing

### RMM for sterility testing of an oncology cell therapy product using ATP bioluminescence

⇒ Dr Michael Miller, Microbiology Consultants LLC

### Validation of a flow cytometry based quantitative lymphocyte immunophenotyping method to qualify cellular products for immune effector cells processing

→ Dr Claude Lemarié, Center for Cell Therapy Marseille

### Microbiological testing of Cell Based Medicinal Products using automated growth based methods

→ Dr Antonio Rodríguez Acosta, Andalusian Initiative for Advanced Therapies

### Challenges for cell-based medicinal products

→ Dr Ilona Kalaszczynska, BMCT

### Filling the gap - from bench to bedside

→ Dr Claudia Papewalis, Valicare

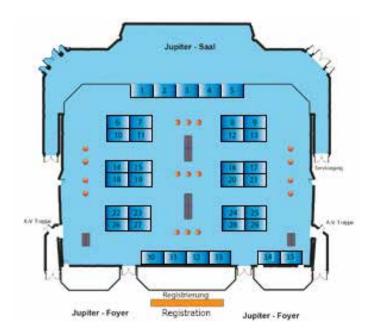
### Cell Based Potency Assays: Analytical Considerations from a Regulatory Perspective

⇒ Dr Sigrid Roosendaal, Quality RA

#### 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 690,- Euro¹
- 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

### Materials for your Marketing

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

- 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

### Sponsoring

### **The Contacts**

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

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.

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.

<sup>&</sup>lt;sup>1</sup> 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 2019

Registration for a stand at the PharmaLab 2019 on 12/13 November 2019 in Difference for the registration of your stand you can also alternatively use the online regist www.pharmalab-congress.com. The charges for a stand are 3.980,- Euro plus (Please note that exhibitors will be responsible for all charges for building and to tion.)	tration form, which you will find on the website at VAT.			
I want to register a stand with the stand number below. (Please note that for cancellation after 31 July 2019 the full registration fee of 3. tions for Fairs/Exhibitions as available on the PharmaLab website do apply.)	980,- Euro will be charged. In addition, the General Terms and Condi-			
The exhibitor plan on the website at www. pharmalab-congress.com is update open and to pick your stand number which you then fill in here:	d every day. Please take a look at this plan to see what spaces are still			
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 (regist	ration as delegate included):			
First & Last Name				
Department				
Street, ZIP & City				
Phone / E-Mail				
Invoice Address				
Participation in Social Event on 12 November 2019: Yes □ No □				
For additional stand personnel a flat rate of € 300, - will be charged per perso together with your registration as exhibitor. The participation of conferences is Stand Personnel – Person 1:	s not included.  Stand Personnel – Person 2:			
Company				
First & Last Name				
Street, ZIP & City				
Phone / E-Mail				
Invoice Address				
Participation in Social Event on 12 November 2019:Yes  No	Yes No No			
Conference Selection for Congress Delegate (not for Stand Personnel):  PharmaLab 2019 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.  11 November 2019: □ ECA – 2nd International Mycoplasma qPCR Testing User Day (inkl. Networking Dinner)  € 490,- (Early Bird Rebate: until 31 August only € 440,-) plus VAT				
☐ ECA – Rapid Microbiological Methods	☐ ECA – Microbiological Real Time Counting and Testing			
ECA – Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14 (Day 1)  ECA – Endotoxin and Pyrogen Testing (Day 1)	☐ ECA – Analytical Procedure Lifecycle Management /			
Revisions to ICH Q2 & the proposed Q14 (Day 1)	Revisions to ICH Q2 & the proposed Q14 (Day 2)			
_	ECA – Endotoxin and Pyrogen Testing (Day 2)			
ECA – Bioanalytics and Bioassays Challenges for Biological Drug Substances and Products	☐ ECA - Testing and Analytics of Cells, Tissues and ATMPs			
Room Reservation:				
Direct room reservation by reservation form! Reservations/bookings can	not be made through Concept Heidelberg. Receipt with confirma-			
<b>tion/invoice.</b> CONCEPT HEIDELBERG has reserved a limited number of rooms in the Crowne with the reservation form you will receive together with the registration confirm	Plaza Düsseldorf/Neuss. You can make your room reservation directly nation. We recommend to register early.			
Court of jurisdiction is Heidelberg, German law is applicable. In addition, the German Lab website at www.pharmalab-congress.com do apply.	eneral Terms and Conditions for Fairs/Exhibitions as available on the			

Signature

City and Date



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

## **Registration Options PharmaLab 2019**

I want to take part in:  □ PharmaLab Pre-Conference "2nd International Mycoplasma qPCR Testing User Day" (11 Nov 2019 including Networking Dinner) - € 490,- (until 31 Aug 2019 only € 440,-) plus VAT □ PharmaLab Conferences on 12 Nov 2019 - € 690,- (until 31 Aug 2019 only € 590,-) plus VAT □ PharmaLab Conferences on 13 Nov 2019 - € 690,- (until 31 Aug 2019 only € 590,-) plus VAT					
	With a one day ticket/two days ticket for the PharmaLab Conferences (12 Nov/13 Nov 2019) 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 (12 November 2019) and I'm primarily interested in the conference:  ECA – Rapid Microbiological Methods  ECA – Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14 (Day 1)  ECA – Endotoxin and Pyrogen Testing (Day 1)  ECA – Bioanalytics and Bioassays - Challenges for Biological Drug Substances and Products				
	☐ I would also like to take part in the Social E	vent on the evening of 12 November.			
	<ul> <li>I would like to attend on day 2 (13 November 2019) and I'm primarily interested in the conference:</li> <li>□ ECA – Microbiological Real Time Counting and Testing</li> <li>□ ECA – Analytical Procedure Lifecycle Management / Revisions to ICH Q2 &amp; the proposed Q14 (Day 2)</li> <li>□ ECA – Endotoxin and Pyrogen Testing (Day 2)</li> <li>□ ECA – Testing and Analytics of Cells, Tissues and ATMPs</li> </ul>				
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 the ri	bill-to-address deviates from the specifications on ght, 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)			

**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.

Street/P.O. Box

City Zip Code

Country

Phone/Fax

CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable without dedutionswithin 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)!

E-Mail (please fill in)

**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.pharmalab-congress.com/privacy-policy.html). 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.