

PharmaLab 2017

Analytics, Bioanalytics and Microbiology

– Congress & Exhibition –

Swissôtel Düsseldorf/Neuss

7/8 November 2017

www.pharmalab-congress.com

Exhibitor Information in the back of the programme

The Conferences

7 November 2017

- ECA – Computerised Systems in Analytical Laboratories
- ECA – Validation Approach of Bioassays using Statistical Methods (Workshop - Day 1)
- ECA – Endotoxin and Pyrogen Testing (Day 1)
- ECA – Rapid Microbiological Methods and Mycoplasma Testing

8 November 2017

- ECA – cGMP Compliance Trends in Analytical Laboratories
- ECA – Validation Approach of Bioassays using Statistical Methods (Workshop - Day 2)
- ECA – Endotoxin and Pyrogen Testing (Day 2)
- ECA – Pharmacopoeial Microbiology Update - USP and EP Developments

Put together your own programme:
■ nearly 50 Lectures
■ over 30 Speakers

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 **European
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Pharmaceutical Quality
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The Congress Objective

On 7 and 8 November 2017 the PharmaLab Congress will take place in Düsseldorf/Neuss for the fifth 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 2017 Overview	
 Key Note 7 November	 A risk-driven Approach to Data Integrity <i>Niek Janssen, ALTRAN Netherlands</i>
Key Note 8 November	 Challenges for QC Networks <i>Dr. Sven M. Deutschmann, Roche Diagnostics, Chairman ECA Pharmaceutical Microbiology Group</i>
Conferences	<u>One day ticket 690,- EUR</u>
7 November 2017 (09.00 – 18.00 h)	
ECA – Computerised Systems in Analytical Laboratories	
ECA – Validation Approach of Bioassays using Statistical Methods (Workshop - Day 1)	
ECA – Endotoxin and Pyrogen Testing (Day 1)	
ECA – Rapid Microbiological Methods and Mycoplasma Testing	
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ECA – Pharmacopoeial Microbiology Update – USP and EP Developments	
Exhibition (7 and 8 November 2017)	
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
- Equipment qualification and calibration
- 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

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.

Target Audience

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 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 (due to the special fees for the congress, ECA membership discounts are not applicable). 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. Charges are payable after receipt of invoice.

Particularities of PharmaLab 2017:

- The registration allows you to access the 6 conferences with close to 50 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 7 November 2017, 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

Swissôtel Congress Centrum Düsseldorf/Neuss
Rheinallee 1
41460 Neuss
Tel.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
emailus.neu02@gchhotelgroup.com

The Organiser

CONCEPT HEIDELBERG – On behalf of the ECA Academy
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D-69007 Heidelberg
Telefon 0 62 21/84 44-0
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www.gmp-navigator.com



Registration

Tuesday, 7 November 2017, 09.00 – 18.00 h
Wednesday, 8 November 2017, 09.00 – 18.00 h
(Registration Monday, 6 November, 19.00 – 20.30 h and
Tuesday, 7 November/Wednesday, 8 November 08.00 – 09.00 h)

The Contacts

For questions regarding content:

Validation Approach of Bioassays using Statistical Methods / Endotoxin and Pyrogen Testing / Microbiological Methods and Mycoplasma Testing / Pharmacopoeial Microbiology Update – USP and EP Developments:

Axel H. Schroeder (Operations Director), Phone +49 (0) 6221 84 44 10,
E-Mail: schroeder@concept-heidelberg.de.

cGMP Compliance Trends in Analytical Laboratories / Computerised Systems in Analytical Laboratories:

Dr Günter Brendelberger (Operations Director), Phone +49 (0) 6221 84 44 40,
E-Mail: brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation, exhibition etc.:

Detlef Benesch, (Organisation), Phone +49 (0) 6221 84 44 45,
E-Mail: benesch@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.

Speakers (as of October 2017)

Ulla Bondegaard	Novo Nordisk, Bagsværd, Denmark Currently responsible for maintaining cross-organisational (and cross-country) laboratory processes.
Peter J. Boogaard	Industrial Lab Automation, The Netherlands Founder Industrial Lab Automation. Member of the ISPE GAMP community.
Peter Cornelis	Toxikon, Belgium R&D scientist and Business Analyst.
Dr Ruth Daniels	Janssen, Belgium Senior Scientist, SME micro. Member of BPOG Low endotoxin recovery Group, and PDA Low endotoxin recovery task force.
Dr Anja Fritsch	Confarma, France Responsible for cell based bioassays (development and routine).
Dr Wolf-Christian Gerstner	Geniu, Hamburg Managing Director.
Christophe Girardey	wega Informatik AG, Switzerland Christophe Girardey manages the group CSV & QA at Wega Informatik. He is involved in different Lab Systems Projects (Lab Execution System, LIMS, ...) as Validation Lead or Business Analyst.
Prof. Edwin van den Heuvel	University of Technology, Eindhoven, The Netherlands Professor at the TU/e department of Mathematics and Computer Science; Professor Medical Statistics at the UMCG (University Medical Center Groningen).
Dr Sunhee Hong	Charles River Microbial Solutions, USA Senior Staff Scientist. Responsible for curating the bacterial and protein coding gene sequence libraries for the Accugenix ID services.
Marleen Hoozemans	MSD, The Netherlands Associate Specialist. Currently working on the development of the Rapid Hybrid Mycoplasma Method.
Dr Patricia Hughes	U.S. Food and Drug Administration Branch Chief (Actg), Division of Microbiology Assessment, OPF/ OPQ/ CDER.
Pieta IJzerman-Boon	MSD, the Netherlands Associate Director Quantitative Sciences/Center for Mathematical Sciences-Europe.
Rick Jakober	Perritt Laboratories, Inc., USA Vice President Laboratory Services. Over 35 years experience in pharmaceutical microbiology, specializing in non-sterile products.
Niek Janssen	ALTRAN Netherlands Senior Consultant Life Sciences with strong background Computerised System Validation (CSV) and Industrial IT.
Dr Sébastien Jouette	EDQM, Strasbourg, France Scientific programme officer in the Biological Division of the European Pharmacopoeia department.
Jan-Oliver Karo	Paul-Ehrlich-Institut – German Federal Institute for Vaccines and Biomedicines Associate Director Quantitative Sciences/Center for Mathematical Sciences-Europe.
Leo Leineweber	Technical Auditor/ Inspector, Münster, Germany Head of Laboratory within the Official Medicines Control Laboratory (OMCL) located at the NRW Centre for Health of the federal state Nordrhein-Westfalen.
Dr Lars Lueersen	CSL Behring Recombinant Facility AG Bern, Switzerland Senior Manager Chemical Quality Control and Global Tech Transfer PM.
Robert Lutskus	Lonza, USA Global Product Delivery Manager for MODA™ EM.
Eric De Maesschalck	UCB, Belgium Head of Global e-Analytics, Corporate Analytical Sciences.
Marine Marius	Sanofi Pasteur, France Leads RMM implementation in ARD Eu for mycoplasma and endotoxin testing.
Dr Danilo Neri	PQE, Italy Validation Project Manager with expertise on Computer System Validation.

Kai Nesemann	Sartorius Lab Instruments GmbH, Germany Junior Product Manager Microbiology. Focus: DNA-based rapid microbe detection methods in microbiological quality control; microbial cultivation media.
Kham Nguyen	Rapid Micro Biosystems, USA Director of Sales.
Dr Karin Nordgren	National Institute of Standards and Control (NIBSC), United Kingdom Head of the Pyrogen Science Group, responsible for BET and MAT testing at the Institute, as well as maintaining established and developing new standards to support the area.
Mathew Paquette	Charles River Laboratories, USA Product- and Technical Specialist.
Robert Porzio	Lonza, USA Global Product Manager. Focusing in instrumentation, automation and software solutions.
Dr Jan Erik Rau	Lonza, Switzerland Senior Scientist and Lab-Manager.
Dr Johannes Reich	MicroCoat Biotechnologie GmbH, Germany Focus on the aggregation and interaction of Lipopolysaccharides as well as the related activities in limulus based detection Systems.
Dr Michael Rieth	Merck, Germany Department Global Regulatory Affairs.
Dr David Roesti	Novartis Pharma Stein/USP, Switzerland Head of the RMM team and the Novartis Pharma expert network in microbiology.
Donald C. Singer	GSK/USP, USA GSK Senior Fellow / Biopharmaceutical GMP Ops at GSK. Vice-Chair of the USP Microbiology Committee of Experts.
Dr Klára Sochorová	Sotio a.s., Czech Republic Working in cell therapy area. Participates in the development from the scientific concept to the medicinal product used in phase III study.
Shabnam Solati	MAT Experiences, The Netherlands Biomolecular Researcher with 25 years of experience, and Monocyte Activation Test (MAT) specialist for over 11 years.
Dr Ingo Spreitzer	Paul-Ehrlich-Institut, Germany Agency for Vaccines and Biomedicines Deputy Head of Section 1/3, "Microbial Safety and Parasitology".
Dr Radhakrishna Tirumalai	USP, USA Global Principal Scientific Liaison-General Chapters in the Science Division. Liaison to the USP Expert Committee on Microbiology.
Dr Astrid Visser	Sanquin Blood Supply Foundation, The Netherlands Coordinates the development of the MAT assay and cells for a robust, reliable assay.
Kevin Williams	BioMerieux, USA Author of the book "EndotoxinS 2".
Dr Friedrich von Wintzingerode	Roche Diagnostics GmbH Senior Manager Microbiology, Head of Roche/Genentech global Endotoxin Expert Group and Roche/Genentech global SME on microbial product contaminations.
Dr Carl-Ulrich Zimmermann	Mycoplasma Biosafety Services, Vienna, Austria Head of Research and Development.

Regulatory Requirements Update (EU and US)

➤ Peter J. Boogaard, Industrial Lab Automation

Audit Trail Review

➤ Niek Janssen, ALTRAN Netherlands

Competing in a Data-driven World - Transforming Scientific Information into Actionable Insights

➤ Peter J. Boogaard, Industrial Lab Automation

Case Study: Entering the Paperless and Digital Era @ UCB BioPharma

➤ Eric De Maesschalck, UCB

Case Study: Validation of a global Lab Execution System

➤ Christophe Girardey, wega Informatik

How Informatics will enable better Quality - One Process, One Record, One Solution

➤ Robert Lutskus, Lonza, USA

**ECA – Validation Approach of Bioassays using Statistical Methods
(Workshop - Day 1)**

Bioanalytics

Module 1: General Part

Module 2: Bioactivity (USP<111>, <1034>, EP 5.3)

ECA – Endotoxin and Pyrogen Testing (Day 1)

Microbiology

FDA's current Thinking on Endotoxin Testing and LER

➤ Dr Patricia Hughes, CDER, FDA

Data Integrity and Human Error Risk Reduction in Endotoxin Testing

➤ Matthew Paquette, Charles River Laboratories

Strategies to overcome Low Endotoxin Recovery using the conventional LAL assay

➤ Dr Ruth Daniels, Janssen

LER effect shown at a multi-vitamin solution

➤ Dr Michael Rieth, Merck

Microbial Contamination Control that includes an Immunological Context

➤ Kevin Williams, BioMerieux

Influence of origin and culturing method of Natural Occuring Endotoxins on Endotoxin

Masking for the LAL and the MAT assay

➤ Peter Cornelis, Toxikon

Case Studies on Endotoxin Masking from a CMO

➤ Dr Jan Erik Rau, Lonza

ECA – Rapid Microbiological Methods and Mycoplasma Testing

Microbiology

Validation of a Rapid Hybrid Mycoplasma Method

➤ Marleen Hoozemans, MSD

Validation of Mycoplasma Testing based on PCR in cellular products

➤ Dr Klára Sochorová, Sotio a.s.

Successful implementation of a RMM for mycoplasma testing as release test on a commercialized product in Europe

➤ Marine Marius, Sanofi Pasteur

Implementation of the MycoTOOL Mycoplasma Real-Time PCR Assay as Early Warning System and for Lot-Release Testing

➤ Dr. Carl-Ulrich Zimmermann, Mycoplasma Biosafety Services

MODA EM Solution and its integration with the Growth Direct system for EM testing

➤ Robert Lutskus, Lonza

➤ Kham Nguyen, Rapid Micro Biosystems

Current Regulatory Expectations for the Microbiological Safety of ATMPs - A Roadmap to Approval

➤ Jan-Oliver Karo, Paul-Ehrlich-Institut – German Federal Institute for Vaccines and Biomedicines

Validation of a qPCR-based test for Gram positive and Gram negative bacteria

➤ Kai Nesemann, Sartorius Lab Instruments

Phylogenetic analysis based on 16S rRNA gene sequence for bacterial identification in the biopharmaceutical industry - Where we are now?

➤ Dr Sunhee Hong, Charles River Microbial Solutions

Current Experiences from GMP Inspections in QC Labs

➤ Leo Leineweber, Technical Auditor / Inspector

Forced Compliance: Turning the FDA Quality Metrics Initiative into Value for your Lab

➤ Dr Wolf-Christian Gerstner, Geniu

Risk-based Approach to Sampling

➤ Ulla Bondegaard, Novo Nordisk

Case Study – Handling OOT Results

➤ Dr Lars Lueersen, CSL Behring Recombinant Facility

ALCOA Metrics for Data Integrity

➤ Dr Danilo Neri, PQE

Update 2017: New challenging ANVISA Requirements to Method Validation and Method Transfer (Brazil)

➤ Ulla Bondegaard, Novo Nordisk

ECA – Validation Approach of Bioassays using Statistical Methods (Workshop - Day 2)

Bioanalytics

Module 3: Development (USP<1032>)

Module 4: Validation (USP<1033>)

ECA – Endotoxin and Pyrogen Testing (Day 2)

Microbiology

Biologics Production: Safety and product quality aspects of bioburden contaminations of non-sterile process intermediates

➤ Dr Friedrich von Wintzigerode, Roche

Latest challenges in the field of endotoxin and pyrogen testing

➤ Dr Johannes Reich, MicroCoat

Regulatory view on MAT

➤ Dr Ingo Spreitzer, Paul-Ehrlich-Institut, Germany Agency for Vaccines and Biomedicines

Comparing key performance aspects of different MAT technologies

➤ Shabnam Solati, MAT Research

Detection of pyrogens with MAT Cell Set, a highly sensitive Monocyte Activation Test based on pooled PBMC

➤ Dr Astrid Visser, Sanguin

Evaluation of the monocyte activation test for the safety testing of meningococcal B vaccine Bexsero: a collaborative study

➤ Dr Karin Nordgren, NIBSC

The Monocyte activation test in routine quality control

➤ Dr Anja Fritsch, Confarma

Importance Of Data Integrity When Testing For Endotoxin

➤ Robert Porzio, Lonza

ECA – Pharmacopoeial Microbiology Update – USP and EP Developments

Microbiology

Overview of Current USP Activities

➤ Radhakrishna Tirumalai, USP

Overview of different revised microbiology-related European Pharmacopoeia chapters

➤ Dr Sébastien Jouette, EDQM

<1229.x> Series of Sterilization Chapters

➤ Don Singer, GSK / USP

Revisions to <1211> and <1222> Sterility Assurance and Parametric Release

➤ Don Singer, GSK / USP

The revised European Pharmacopoeia chapter 5.1.6 related to alternative methods for control of microbiological quality

➤ Dr Sébastien Jouette, EDQM

Current USP Perspectives on a Rapid Sterility Test

➤ Dr David Roesti, Novartis/USP

Current USP perspectives on Objectionable Organisms

➤ Radhakrishna Tirumalai, USP

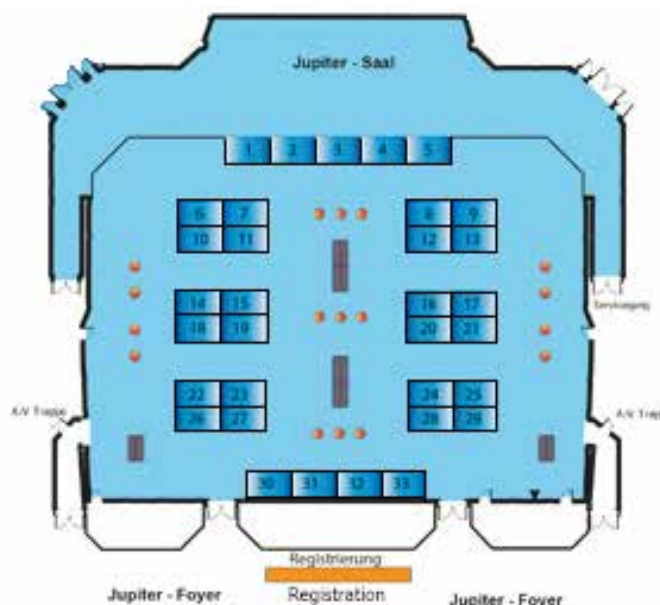
Implementation of USP <1115> in the Non-Sterile Pharma Manufacturing Environment

➤ Rick Jakober, Perritt Laboratories Inc.

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

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

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

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 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:
Detlef Benesch (Organisation Head), Phone +49 (0) 6221 84 44 45,
E-Mail: benesch@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 2017

Registration for a stand at the PharmaLab 2017 on 7/8 November 2017 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 2017 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 7 November 2017: 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 7 November 2017: Yes No Yes No

Conference Selection for Congress Delegate (not for Stand Personnel):

PharmaLab 2017 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.

7 November	<input type="checkbox"/> ECA – Computerised Systems in Analytical Laboratories	8 November	<input type="checkbox"/> ECA – cGMP Compliance Trends in Analytical Laboratories
	<input type="checkbox"/> ECA – Validation Approach of Bioassays using Statistical Methods (Workshop - Day 1)		<input type="checkbox"/> ECA – Validation Approach of Bioassays using Statistical Methods (Workshop - Day 2)
	<input type="checkbox"/> ECA – Endotoxin and Pyrogen Testing (Day 1)		<input type="checkbox"/> ECA – Endotoxin and Pyrogen Testing (Day 2)
	<input type="checkbox"/> ECA – Rapid Microbiological Methods and Mycoplasma Testing		<input type="checkbox"/> ECA – Pharmacopoeial Microbiology Update: USP and EP Developments

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 Options PharmaLab 2017

- Attending the PharmaLab Conferences – One Day Ticket for € 690,-
- Attending the PharmaLab Conferences – Two Days Ticket for € 1.380,-

With a one day ticket/two days ticket 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 (7 November 2017)** and I'm primarily interested in the conference:

- ECA – Computerised Systems in Analytical Laboratories
- ECA – Validation Approach of Bioassays using statistical Methods (Workshop - Day 1)
- 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 7 November.

- I would like to attend on **day 2 (8 November 2017)** and I'm primarily interested in the conference:

- ECA – cGMP Compliance Trends in Analytical Laboratories
- ECA – Validation Approach of Bioassays using statistical Methods (Workshop - Day 2)
- ECA – Endotoxin and Pyrogen Testing (Day 2)
- ECA – Pharmacopoeial Microbiology Update – USP and EP Developments

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 week 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 <http://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.