PharmaLab 2019

Analytics, Bioanalytics and Microbiology
– Congress & Exhibition –

Crowne Plaza Düsseldorf/Neuss

12/13 November 2019

www.pharmalab-congress.com

Exhibtor Information in the back of the programme

The Conferences

NEW: PharmaLab App
to install scan the code

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

Official Media Partners

European Biotechnology
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EPR
EUROPEAN PHARMACEUTICAL REVIEW

CONCEPT HEIDELBERG

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

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

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

	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**

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 € 690,- plus VAT, for the two days ticket € 1.380,- plus VAT. They include lunch and beverages during the conferences and in breaks as well as the social event on the evening of the first congress day (Due to the special fees for the congress, ECA membership discounts are not applicable).

The visit of the pre-conference on 11 November 2019 for € 490,- 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
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The Contacts

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E-Mail: schroeder@concept-heidelberg.de

For questions regarding reservation, hotel, organisation, exhibition etc.:
Ronny Strohwald, (Organisation), Tel.+49 (0) 6221/84 44-51,
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NEW: The PharmaLab App

Just download the new PharmaLab app to your smartphone or tablet and have everything at hand: agenda, presentations, speaker backgrounds, notifications and more... To install the app, please scan the QR code or search for "Pharma Events" in the Apple or the Google Play Store.

The Official Media Partners

European Biotechnology
Life Sciences and Industry Magazine

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

EPR

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

Key Note Speakers (as of September 2019)	
Dr Jürgen Balles	**Labor LS,** Senior Manager Chemical Quality Control und Global Tech Transfer PM.
Ingo Grimm	**Labor LS,** Sales & Services.
Dr Joachim Ermer	**Sanofi-Aventis Deutschland,** Head of QC Lifecycle Management Frankfurt Chemistry.
Dr Thomas Meindl	**Labor LS,** Division Manager.

Speakers (as of September 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,** Director Product Development & Supply. Member of various analytical teams (e.g. EFPIA, USP and BP) supporting the development of ICHQ2(R2)/Q14.
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.
Chiara Celli	**Merck, Italy,** Scientist Microbiological ID.
Dr Jörg Degen	**Eurofins BioPharma Product Testing, Germany,** Head of Microbiology.
Dr Marja Claassen–Willemse	**MSD, The Netherlands,** Senior microbiological specialist, Microbiology Center of Excellence.
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 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.
Dr Christie English	**Mycoplasma Experience**, Scientist - Molecular Biology
Thomas Fechner	**Agilent Technologies, Germany,** Principal Scientist.
Dr Anja Fritsch	**Confarma, France,** Responsible for cell based bioassays (development and routine).
Stefan Gärtner	**Labor LS, Germany,** Head of Department Sterility Testing, Member ECA Mat Task Force.
Barbara Gerten	**Merck, Germany,** Chairwoman DIN Working Group Microbiological Food Testing incl. Rapid Methods.
Dr Eelo Gitz	**Sanquin Reagents , The Netherlands,** Project manager product development.
Dr Marcus Gutmann	**Microcoat Biotechnologie, Germany**, Project Leader Endotoxin Services.
Dr Norbert Handler	**RD&C Research, Development & Consulting GmbH, Austria,** Managing Director.
Dr Qing He	**Chinese National Institutes for Food and Drug Control,** Pharmacology Division.
Dr Jessica Hankins	**U.S. Food and Drug Administration**
Patrick Jackson	**GSK, UK,** Investigator in CMC-Analytical.
Dr Gerd Jilge	**Boehringer Ingelheim, Germany,** Quality Control. Member of the EDQM expert group 11 and Board Member of the ECA QC Group.
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 Commission.
Dr Prasanna Khot	**Charles River Laboratories, USA,** Senior Research Scientist Microbial Solutions.
Annette Kunz	**CSL Behring, Switzerland,** Manager Monitoring.
Dr Claude Lemarié	**Center for Cell Therapy Marseille, France,** QC Management.
Thomas Ludwig	**VelaLabs – A Tentamus Company, Austria,** Group Leader for cell-based assays.
Marine Marius	**Sanofi Pasteur, France,** Scientist in Analytical R&D Microbiology.
Bob McDowall	**R.D. McDowall Limited, UK,** Director.
Dr Michael J. Miller	**Microbiology Consultants, USA,** Global expert in rapid methods, validation and pharmaceutical microbiology.
Dr Hikaru Mizimura	**Seikagaku, Japan**
Dr Félix A. Montero Julian	**bioMerieux, France,** Scientific Director.
Dr Alexandra Müller-Scholz	**Sartorius Stedim Biotech, Germany**, Scientist - Applications for Molecular Biology.
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.
Kham Nguyen	**Rapid Micro Biosystems, USA,** QC Scientist.
Diarmaid O'Riordan	**Pfizer, Ireland,** QC Microbiologist.
Dr Claudia Papewalis	**Valicare, Germany,** Senior GMP Consultant.
Katrin Pauls	**Lonza, Germany,** Market Development and Scientific Affairs Manager.
Joseph Pierquin	**Redberry, France,** Chief Technical Officer.
Dr Johannes Reich	**Microcoat Biotechnologie, Germany,** General Manager.
Nicola Reid	**Charles River Laboratories, UK,** Senior Product Manager.
Stéphanie Richard	**Sanofi Pasteur, France,** Scientist-Analitycal Sciences Department-Immunology platform.

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.
Christiana Schnitzler	**Boehringer Ingelheim, Germany,** Head Mycoplasma Laboratory.
Dr Gerold Schwarz	**Bruker Deltronics, Germany,** Manager Application Support.
Prof. 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 Biomedicine**s Deputy Head of Section 1/3, "Microbial Safety and Parasitology".
Natascha Staub	**Mibelle, Switzerland.** Microbiological QC.
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.
Anders Thorn	**Novo Nordisk, Denmark,** Quality Control Specialist.
Jonas van den Berg	**Roche, Germany,** Validation of the Celsis-based Alternative Sterility Test.
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 – A Regulator´s View on ATMPs
➲ Jan-Oliver Karo, Paul-Ehrlich Institut

MycoTOOL – Method Development and Generic Validation Strategy
➲ Christiana Schnitzler, Boehringer Ingelheim

Comparative Evaluation of 2 real-time PCR-based Mycoplasma Kits
➲ Dr Christie English, Mycoplasma Experience

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
➲ Dr Alexandra Müller-Scholz, Sartorius Stedim Biotech

Mycoplasma detection system and its verification
➲ Andrej Steyer, University of Ljubljana (co-author: Dr Marjanca Blas, Sandoz, Slovenia)

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

Congress Key Note

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, Rapid Micro Biosystems

A Practical Guide on how to demonstrate a significant return of investment 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

Picture: Labor LS

The Conferences
12 November 2019

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 USP, 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

Proficiency Test Program for MAT
➲ Dr Ruth Röder, Microcoat Biotechnologie

MAT implementation: from validation to use in routine in a GMP QC Lab
➲ Chiara Celli, Merck

MAT - Ready for GMP Routine?
➲ Stefan Gärtner, 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

Regulatory Requirements of analytical procedure and validation
➲ Dr Nobert Handler, RD&C Research, Development & Consulting

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 & cell-based bioassays
➲ Thomas Ludwig, VelaLabs – A Tentamus Company

Process for automatization of a Bioassay
➲ Dr Marcus Gutmann, Microcoat Biotechnologie

Application of fast and non-destructive analysis techniques in quality and in-process control
➲ Prof. Dr. Hartwig Schulz, formerly Julius Kühn-Institut (JKI)

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

Implementation of a Microbial Detection Analyzer For Real-Time Monitoring of Microbial Contamination for Purified Water
➲ Natascha Staub, Mibelle

Biofluorescent Particle Counting (BFPC) for continuous monitoring in aseptic manufacturing
➲ Dr Marja Claassen-Willemse, Merck

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

IMD-W "In-line system for purified water systems" and other devices for rapid water bioburden analyses
➲ Dr Sven Deutschmann, Roche Diagnostics

Calculating alert levels and trending of microbiological data
➲ Dr David Roesti, Novartis

New Generation of Solid Phase Cytometry for Rapid Detection of Microbiological Contaminants in Water Samples
➲ Joseph Pierquin, Redberry

Picture: VelaLabs – A Tentamus Company

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
➲ Silviya Dimitrova, Teva
➲ 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

LER Hold-Time studies
➲ Anders Thorn, Novo Nordisk

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

4 Factors affecting the recovery of endotoxin
➲ Dr Johannes Reich, Microcoat Biotechnologie

Application of a recombinant three-factor chromogenic reagent, PyroSmart, for bacterial endotoxins test
➲ Dr Mizumura Hikaru, Seikagaku Corporation
➲ Veronika Wills, ACC

Evaluation of rFC for product testing
➲ Marine Marius, Sanofi

Picture: Charles River Laboratories

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

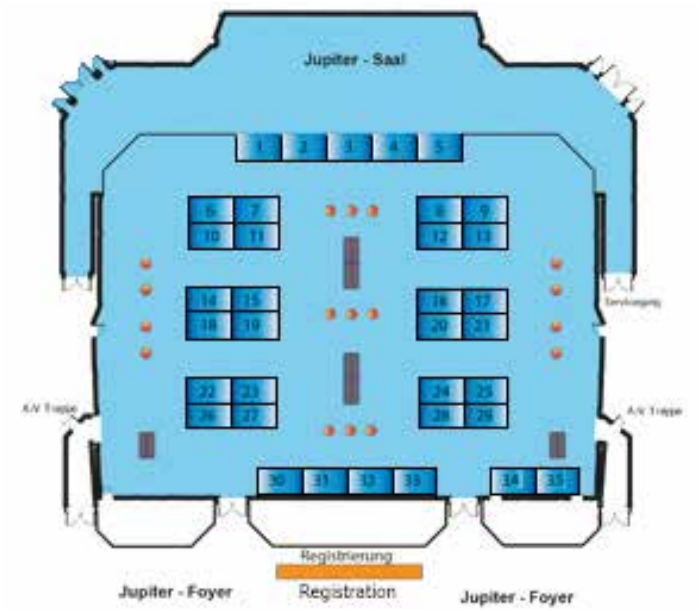
Filling the gap – from bench to bedside
➲ Dr Claudia Papewalis, Valicare

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

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

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

The Contacts

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.

[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 2019

Registration for a stand at the PharmaLab 2019 on 12/13 November 2019 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 2019 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 12 November 2019: 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 12 November 2019:Yes ☐ No ☐	Yes ☐ 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,- plus VAT

12 November	☐ ECA – Rapid Microbiological Methods	**13 November**	☐ ECA – Microbiological Real Time Counting and Testing
	☐ ECA – Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14 (Day 1)		☐ ECA – Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14 (Day 2)
	☐ ECA – Endotoxin and Pyrogen Testing (Day 1)		☐ 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 cannot be made through Concept Heidelberg. Receipt with confirmation/invoice.
CONCEPT HEIDELBERG has reserved a limited number of rooms in the Crowne Plaza Düsseldorf/Neuss. You can make your room reservation directly with the reservation form you will receive together with the registration confirmation. We recommend to register early.

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

City and Date

Signature

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

Registration Form:
CONCEPT HEIDELBERG
Rischerstraße 8
69123 Heidelberg, Germany

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

E-Mail:
info@concept-heidelberg.de

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

Registration Options PharmaLab 2019

I want to take part in:

- ☐ **PharmaLab Pre-Conference "2nd International Mycoplasma qPCR Testing User Day" (11 Nov 2019 including Networking Dinner) - € 490,- plus VAT**
- ☐ **PharmaLab Conferences on 12 Nov 2019 – € 690,- plus VAT**
- ☐ **PharmaLab Conferences on 13 Nov 2019 – € 690,- 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 Event on the evening of 12 November.

☐ I would like to attend on **day 2 (13 November 2019)** and I'm primarily interested in the conference:
- ☐ 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

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 deduction-swithin 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.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.

pe/17092019