

PharmaLab 2014

Analytics, Bioanalytics und Microbiology – Congress & Exhibition –

Swissôtel Düsseldorf/Neuss – 19/20 November 2014

www.pharmalab-congress.com



**Exhibitor Information
on the last two pages**

The Conferences

19 November 2014

- ECA – Handling of Microbiological OOS/OOL
- ECA – Bioassays – Performance and Statistical Interpretation
- ECA – cGMP Compliance Trends in Analytical Quality Control
- ECA – Endotoxin and Pyrogen Testing (Day 1)

20 November 2014

- ECA – Stability Testing of Biopharmaceuticals
- ECA – Endotoxin and Pyrogen Testing (Day 2)
- ECA – Laboratory Informatics – Update 2014

**CONCEPT
HEIDELBERG**

Pharmaceutical Quality
Training. Conferences. Services.

Media Partner:

**European
Biotechnology
News**
Science & Industry

The Congress Objective

On 19 and 20 November 2014 the PharmaLab Congress will take place in Düsseldorf/Neuss for the second time. This new 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 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 2014 Overview	
Conferences	<u>One day ticket 690,- EUR</u>
19 November 2014	
ECA – cGMP Compliance Trends in Analytical Quality Control	
ECA – Bioassays – Performance and Statistical Interpretation	
ECA – Handling of Microbiological OOS/OOL	
ECA – Endotoxin and Pyrogen Testing (Day 1)	
20 November 2014	
ECA – Laboratory Informatics – Update 2014	
ECA – Stability Testing of Biopharmaceuticals	
ECA – Endotoxin and Pyrogen Testing (Day 2)	
Exhibition (19 and 20 November 2014)	

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 requirements and actual interpretation of EU GMP Annex 11)
- 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 the PharmaLab 2014:

- The registration allows access to the 6 conferences with 45 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 the 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, bio analytics, and microbiology at the exhibition.
- Take advantage of the 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 19 November 2014, 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@swissotel-duesseldorf.de

The Organiser

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



For questions regarding content:

Handling of Microbiological OOS/OOL / Bioassays – Performance and Statistical Interpretation/ Endotoxin & Pyrogen Testing / Stability Testing of Microbiologicals:
Axel H. Schroeder (Operations Director), Phone +49 (0) 6221 84 44 10,
E-Mail: schroeder@concept-heidelberg.de.

cGMP Compliance Trends in Analytical Quality Control / Laboratory Informatics:

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 News reports on all of 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

Prof. Tudor Arvinte, Ph.D.	Professor, Department of Biopharmaceutics, University of Geneva, Switzerland CEO, Therapeomic, Inc.
Dr Paola Berin	F.I.S., Milano, Italy Responsible for lab x-ray powder diffractor and x-rdp evaluation as well as for cleaning validation management.
Ulla Bondegaard	Novo Nordisk, Bagsværd, Denmark Responsible for maintaining cross-organisational (and cross-country) laboratory processes.
Dr Peter Brügger	Novartis Pharma AG, Basel QC Expert Biological Analytics.
Emmanuelle Charton, Ph. D.	European Directorate for the Quality of Medicines and HealthCare (EDQM) Deputy Head, European Pharmacopoeia Department.
Dr Orla Cloak	Lonza, USA Microbiologist and Commercial Development Manager.
Peter Cornelis	Toxikon Europe NV, Leuven, Belgium Department Supervisor Microbiology & In Vitro Toxicology.
Michael E. Dawson, Ph.D.	RAC, Associates of Cape Cod, Inc., USA Director of Regulatory Affairs at Associates of Cape Cod, Inc. (ACC).
Dr Sven M. Deutschmann	Roche Diagnostics GmbH, Germany Director of the Micro- and Cellbiology QC Department in the Pharma Division.
Dr Wolfgang Eder	Roche Diagnostics GmbH, Penzberg, Germany Manager Quality Control.
Dr Markus Fido	Vela Laboratories, Vienna, Austria Founder and Chief Executive Officer.
Dr Thomas Flad	Protagen Protein Services, Heilbronn, Germany Global Director Business Development.
Dr Anja Fritsch	Confarma France SARL Head of Pharmacology / Toxicology / Cell Biology.
Dr Tino Galgon	IDT Biologica GmbH, Dessau-Roßlau Director Pharmaceutical Development.
Dr Aline Gauffre	Lilly France SAS, Illkirch, France Black belt (lean 6 sigma); QC manager in charge of the maintenance and qualification of the analytical equipment.
Dr Karine Gonzales	Vela Laboratories, Vienna, Austria Senior Scientist at Dept. Assay Development.
Katharina Halbig	Labor L+S AG, Bad Bocklet, Germany Divison Head, Microbiological Testing of Sterile Products.
Dr. Ulrike Herbrand	Charles River Biopharmaceutical Service GmbH, Erkrath, Germany Scientific Officer Biosafety & Bioassay Services, Biologics Testing Solutions.
Foster Jordan	Charles River Laboratories, USA Corp. Senior Vice President, Charles River Endotoxin and Microbial Detection.
Dr Jon S. Kauffman	Eurofins Lancaster Laboratories, Pennsylvania, USA Senior Director, Biopharmaceutical Services.
Nicola Kingswell	Intertek Lifesciences, United Kingdom Biotechnology Team Leader.

Dr Bettina Lauer	Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany Manager Quality Control Microbiology.
Dr Manuela Leitner	AGES – Austrian Agency for Health and Food Safety Quality Assessor for plasma derived Medicinal Products and Plasma Master File.
Dr. Johannes Grillari	Assoc. Prof. DI Dr. Johannes Grillari, CSO of Evercyte GmbH, Vienna, Austria Co-founder of TAmiRNA GmbH and Scientific Advisor and Co-founder and CSO of Evercyte.
Eric De Maesschalck	UCB, Brain, Belgium Head of Global e-Analytics, Corporate Analytical Sciences.
Dr Frans A. Maris	MSD, Oss, The Netherlands Head of the Quality Control Analytical Chemistry laboratories for finished products.
Dr Bob McDowall	McDowall Consulting, Bromley, Kent, UK Principal of McDowall Consulting.
Dr Daniel Müller	GMP-Inspector, Regierungspräsidium Tübingen Regional authority in Tübingen, Baden-Württemberg, Germany.
Robert J. Mello, Ph.D.	US Food and Drug Administration (FDA), Office of Pharmaceutical Science/CDER Senior Microbiology Reviewer , New Drug Microbiology Staff.
Dr Marcus Mreyen	Protagen Protein Services, Heilbronn Director business development.
Johannes Reich	University Regensburg, Germany PhD Student with focus on the aggregation and interaction of Lipopolysaccharides as well as the related activities in limulus based detection systems.
Dr Michael Rieth	Merck Millipore, Darmstadt, Germany Global Regulatory Management Biological Materials.
DI Markus Roucka	Vela Laboratories, Vienna, Austria Head of Laboratory, Dept. Assay Development.
Dr. Tara Sanderson	SGS M-Scan Ltd, United Kingdom Life Science Services, Formulation Services Manager , Formulation & Stability Group..
Dr Maximillian Schlicht	Labor L+S AG, Germany Head of Divison Sterile Products Testing.
Dr Petra Schlick	AGES – Austrian Agency for Health and Food Safety Quality Assessment with Specialisation on Vaccines (Human & Veterinary), Recombinant Products, Plasma Products.
Vera Simic	Medicines and Medical Devices Agency of Serbia Scientist at National Control Laboratory- Biological Laboratory.
Dr Ingo Spreitzer	Paul-Ehrlich-Institut, German Agency for Vaccines and Biomedicines, Langen, Germany Deputy Section of Microbial Safety.
Dr Herbert Weindorf	Sandoz international, Industriepark Höchst Frankfurt Global GMP Auditor.
Dr Robert Weiss	Baxter AG, Vienna, Austria Head of Quality Control.
Dr Friedrich von Wintzingerode	Roche Diagnostics GmbH Penzberg, Germany Group Leader Microbiological IPC and Analytics for Release.

Recent Changes in US Law, USP General Chapters and FDA Enforcement

➤ Dr Bob McDowall, McDowall Consulting, UK

Case Study: Handling of OOT Results

➤ Dr Robert Weiss, Baxter, Vienna

Case Study: Hot Topics in QC Laboratories

➤ Dr Robert Weiss, Baxter, Vienna

GMP and Quality Oversight during Audits and Inspections in QC Laboratories

➤ Dr Herbert Weindorf, Sandoz International

Guidelines regarding Transfer of Analytical Procedures

➤ Ulla Bondegaard, Novo Nordisk, Denmark

Increased Focus on Reducing Foreign Matter in Pharmaceutical Products: Analytical Challenges

➤ Dr Frans Maris, MSD, The Netherlands

New FDA Draft Guidance: Analytical Procedures and Methods Validation for Drugs and Biologics (Feb: 2014) – Requirements and Challenges

➤ Ulla Bondegaard, Novo Nordisk, Denmark

What are Raw Data and Complete Data in EU and FDA regulations?

➤ Dr Bob McDowall, McDowall Consulting, UK

ECA – Bioassays – Performance and Statistical Interpretation

Regulatory Expectations and Experiences

➤ Dr Petra Schlick, AGES

Pharmacokinetics

➤ Dr Karine Gonzales, Vela

Immortalization of primary human cells: a platform technology for generating relevant and standardizable cell lines

➤ Dr. Johannes Grillari, Evercyte

Characterization of Biosimilars with defined Bioassays

➤ DI (FH) Markus Roucka, Vela

Influenza Vaccine – SRD Method in Haemagglutinin antigen content determination

➤ Vera Simic, Medicines and Medical Devices Agency of Serbia

Bioactivity Testing for Protein Therapeutics

➤ Dr Ulrike Herbrand, CRL

HCP Assay – New tools for an ongoing challenge

➤ Dr Thomas Flad, Protagen

Importance of Orthogonal Methods in the Analysis of Protein Aggregation: Case Studies

➤ Prof Dr Tudor Arvinte, University Basle

ECA – Handling of Microbiological OOS/OOL

Microbiological 'deviations' - regulatory expectations & experience

➤ Dr Daniel Müller, GMP Inspector

OOS in microbial count determination

➤ Dr Michael Rieth, Merck Serono

Pharmaceutical Water Qualities – Handling of OOS/OOL Results

➤ Dr Wolfgang Eder, Roche Diagnostics

How to handle Monitoring Deviations

➤ Dr Bettina Lauer, Vetter Pharma-Fertigung

OOS on Sterility testing

➤ Dr Bettina Lauer, Vetter Pharma-Fertigung

Positive Sterility Testing – OOS or secondary Contamination

➤ Katharina Halbig, Labor L+S

Microbial Identification – An important part of an OOS Root Cause Analysis

➤ Dr Wolfgang Eder, Roche Diagnostics

ECA – Endotoxin and Pyrogen Testing (Day 1)

An update on current European Pharmacopoeia activities in the field of bacterial endotoxin, pyrogen and monocyte activation tests

➤ Emmanuelle Charton, Ph. D., EDQM

Revision of Ph. Eur.-Chapter 5.1.10 'Guideline for Using the Test for Bacterial Endotoxins'

➤ Dr Sven M. Deutschmann, Roche Diagnostics

Current Pharmacopoeial Developments on MAT

➤ Dr Ingo Spreitzer, Paul-Ehrlich Institut

Cryopreservation of human PBMC for pharmacopoeial MAT

➤ Dr Peter Brügger, Novartis

Detection and quantification of pyrogens by monocyte activation test

➤ Dr Anja Fritsch, Confarma

Alternative recombinant Factor C Method for Endotoxin Detection

➤ Dr Orla Cloak, Lonza

Low Endotoxin Recovery (LER) – an FDA Reviewer's Perspective

➤ Dr Robert Mello, FDA

The Journey of Endotoxin Testing – Past, Present, Future

➤ Foster Jordan, Charles River Laboratories

Data Standards for Analytical Instruments: Where have we come from and where are we going?

➤ Dr Bob McDowall, McDowall Consulting, UK

Hot Topic in EU GMP Annex 11 – Audit Trails

➤ Dr Bob McDowall, McDowall Consulting, UK

Data Integrity in the QC Laboratory: Changing Mind Set

➤ Dr Aline Gauffre, Lilly France

Designing Paperless Lab Data Processes and Compliances through Implementation of integrated e-Analytics @ UCB

➤ Eric De Maesschalck, UCB, Braine, Belgium

The Role of Chromatography Data Systems in QC Laboratory Data Falsification Cases (and how to prevent this)

➤ Dr Bob McDowall, McDowall Consulting, UK

An Example of LIMS Customisations in QC Lab and its Connection with Site MES and ERP Systems

➤ Dr Paola Berin, F.I.S, Milano, Italy

LIMS Validation – key Issues of Project Phases

➤ Dr Bob McDowall, McDowall Consulting, UK

ECA – Stability Testing of Biopharmaceuticals

Bioanalytics

Stability studies - shelf-life, activities and essential documents

➤ Dr. Markus Fido, Vela Laboratories

Regulatory Requirements

➤ Dr. Manuela Leitner, AGES

Biotech: Forced Degradation Studies

➤ Dr. Tara Sanderson, SGS M-Scan

Critical Success Factors of a Biologics Stability Program

➤ Dr. Jon S. Kauffman, Eurofins Lancaster Laboratories

Stability Testing in Biosimilar Development – additional aspects to be considered

➤ Dr. Marcus Mreyen, Protagen

Stability Testing – Experiences

➤ Ashleigh Wake, Intertek Lifesciences

Optimising Packaging and Storage Conditions for Biotech Products

➤ Dr. Tino Galgon, IDT



Image: Vela Labs

ECA – Endotoxin and Pyrogen Testing (Day 2)

Microbiology

Low Endotoxin Recovery (LER): Assuring the Validity of Endotoxin Test Results

➤ Dr Michael Dawson, Associates of Cape Cod

A comparative study of Pyrogen detection assays and the effect on Endotoxin Masking and Inhibition or Enhancement

➤ Peter Cornelis, Toxikon

Endotoxin Masking

➤ Dr Friedrich von Wintzingerode, Roche Diagnostics

De-Masking techniques for endotoxin detection in biopharmaceuticals

➤ Johannes Reich, University Regensburg

OOS in endotoxin determination

➤ Dr Michael Rieth, Merck

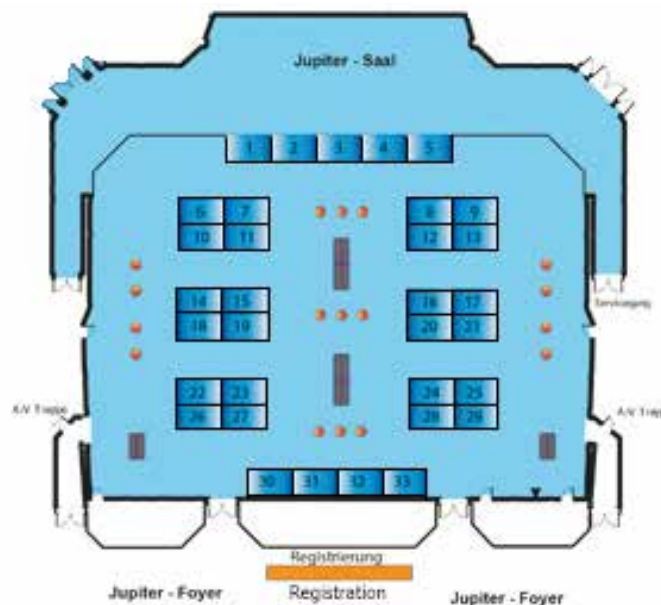
Sample Preparation for LAL Test on Oily Formulation

➤ Dr Enrico Barth, L+S

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
- 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 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 – 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; online registration necessary. 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 2014

Registration for a stand at the PharmaLab 2014 on 19/20 November 2014 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.

I am aware that I will be charged 50% of the registration fee if I cancel this registration before 31 July 2014 and that the full registration fee of 3.980,- Euro will be charged for cancelling after that date.

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 19 November 2014: 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 19 November 2014: Yes No Yes No

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

PharmaLab 2014 delegates are free to attend the conferences they are interested in. To set up the conference rooms, though, we would appreciate it if you let us know what conference you are specifically interested in – please mark your choice per day below.

19 November	<input type="checkbox"/> ECA – cGMP Compliance in Analytical Quality Control	20 November	<input type="checkbox"/> ECA – Laboratory Informatics – Update 2014
	<input type="checkbox"/> ECA – Bioassays – Performance and Interpretation		<input type="checkbox"/> ECA – Stability Testing of Biopharmaceuticals
	<input type="checkbox"/> ECA – Handling of Microbiological OOS/OOL		<input type="checkbox"/> ECA – Endotoxin and Pyrogen Testing (Day 2)
	<input type="checkbox"/> ECA – Endotoxin and Pyrogen Testing (Day 1)		

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.

City and Date

Signature

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

