PharmaLab 2013

Analytics, Bioanalytics and Microbiology
– Congress & Exhibition –

Swissôtel Düsseldorf/Neuss – 13/14 November 2013
www.pharmalab-congress.com

Set up your own programme –
- **out of 45 lectures**
- **from 40 speakers**

The Conferences

13 November 2013

- ECA – Trends in Chromatography (HPLC/UHPLC)
- ECA – Bioassays
- ECA – Current Developments and Trends in Sterility Testing

14 November 2013

- ECA – Laboratory Informatics – Update 2013
- ECA – Endotoxin and Pyrogen Testing
- ECA – Microbial Safety of Raw Materials and Excipients

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The Congress Objective

On 13 and 14 November 2013 the PharmaLab Congress will take place in Düsseldorf/ Neuss for the first 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 2013 Overview	
Conferences	One day ticket 690,- EUR
13 November 2013	
ECA – Trends in Chromatography (HPLC/UHPLC)	
ECA – Bioassays	
ECA – Current Developments and Trends in Sterility Testing	
14 November 2013	
ECA – Laboratory Informatics – Update 2013	
ECA – Endotoxin and Pyrogen Testing	
ECA – Microbial Safety of Raw Materials and Excipients	
Exhibition (13 and 14 November 2013)	

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 test
- 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 € 1.190,- 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 2013:

- 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 13 November 2013, 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 European Compliance Academy (ECA)
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

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For quesetions regarding content:
Bioassays / Curent Development & Trends in Sterility Testing / Endotoxin & Pyrogen Testing / Microbial Safety:
Axel H. Schroeder (Operations Director), Phone +49 (0) 6221 84 44 10,
E-Mail: schroeder@concept-heidelberg.de.

Trends in Chromatography / 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, Jessica Stürmer, Ronny Strohwald (Organisation),
Phone +49 (0) 6221 84 44 -45, -43, -51, E-Mail: benesch@concept-heidelberg.de,
stuermer@concept-heidelberg.de, strohwald@concept-heidelberg.de.

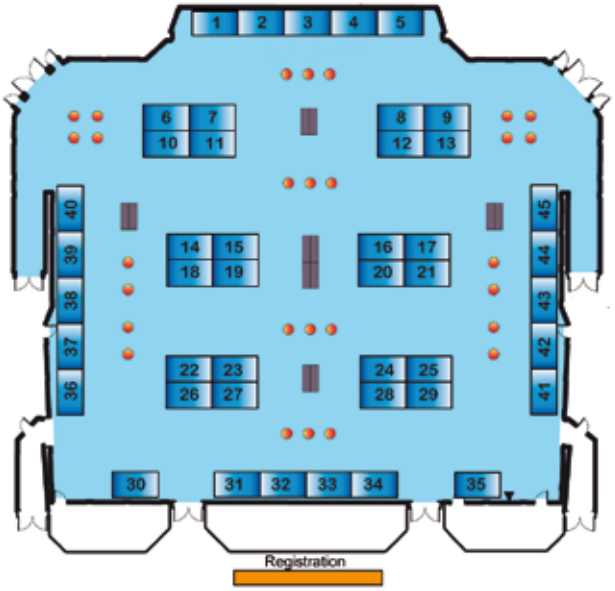
The Media Partner

European Biotechnology Science & Industry News

European Biotechnology News reports monthly on all of the latest political, economic and technical developments in the life sciences sector in all 27 EU countries plus Switzerland and Norway. To find out more please visit www.eurobiotechnews.eu.

The parallel Exhibition

The large PharmaLab Exhibition on both days will be another ideal forum for the exchange of information and experience. It is located between the conference rooms. Nearly 40 exhibitors will present latest systems and methods as well as their services and will allow a comparison of available equipment.



Speakers

Dr Mauro Anglana
Merck Millipore, Vimodrone, Italy
Regional Marketing Manager Europe, BioMonitoring, Trainer on Bioburden and Sterility testing.

Prof Tudor Arvinte
Ph.D., Professor, Department of Biopharmaceutics, University of Geneva, Switzerland
CEO, Therapeomic, Inc.

Dr Dirk Badura
Carbogen Amcis, Switzerland
Leading the Department Quality Systems, also responsible for the computer and software validation.

Dr Jürgen Balles
Labor L+S AG, Bad Bocklet, Germany
Section Head Biological and Microbiological Quality Control.

Martin Blüggel
CBO, Protagen Protein Services GmbH
Author of more than 35 scientific publications and cofounder of Protagen.

Dr Cornelia Bodinet
Schaper – Brümmer, Salzgitter, Germany
Head of Pharmaceutical and Microbiological Laboratories, Member of the executive board.

Ulla Bondegaard
Novo Nordisk, Denmark
Responsible for cross-organisational lab processes incl. lab GMP and computerised systems.

Peter J. Boogaard
Industrial Lab Automation, Netherlands
Founder.

Dr Olivier Chancel
Merial, Toulouse, France
Head of Perfomance and Pharmaceutical Support.

Peter Cornelis
Toxikon Europe NV, Leuven, Belgium
Department Supervisor Microbiology & In Vitro Toxicology.

Dr Michael E. Dawson
RAC, Associates of Cape Cod, Inc.
Director of Regulatory Affairs at Associates of Cape Cod, Inc. (ACC).

Dr Anja Fritsch
Confarma France, SARL, Homburg, France
Chief Scientific Officer - Development of cell-based Assay Systems for the Analysis of Variety of Biological Reactions.

Dr Marcel Goverde
MGP Consulting, Switzerland
Consultant and Trainer on Microbiology and Quality.

Dr Steffen Groß
Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines
Scientific Assessor and Laboratory Head Section Monoclonal and Polyclonal Antibodies.

Dr Rajesh Gupta
Biologics Quality & Regulatory Consultants, LLC
Consultant Vaccinologist and Microbiologist, formerly FDA/CBER.

Dr Ulrike Herbrand	**Charles River Biopharmaceutical Services GmbH, Erkrath, Germany** Scientific Officer in the Bioanalytics Department.
Dr Christoph Höppner	**BSL Bioservice Scientific Laboratories, Munich, Germany** Head of the Department Analytics, Bioanalytics and Biological Safety.
Dr David Jones	**Rapid Micro Biosystems, Bedford, USA** Technical Services Director.
Dr Timo Krebsbach	**Labor L+S AG, Bad Bocklet, Germany** Marketing and Sales Manager, prior Manager Sterility Testing.
Dr Bettina Lauer	**Vetter Pharma Fertigung GmbH & Co. KG, Ravensburg, Germany** Manager Quality Control Microbiology.
Dr Joanna Mania	**DADA Consultancy, BV, Netherlands** Senior Consultant Quality and Regulatory Affairs.
Karl Heinz Menges	**RP Darmstadt, Germany** European GMP Inspector, Head of the German Inspectors Computerised System Working Group; has contributed to Annex 11.
Cyril Mounier	**Getinge Life Sciences, Vendome, France** Validation Manager, Getinge La Calhene, Validation Department.
Dr Andreas Nechansky	**Vela Laboratories, Vienna, Austria** Founder/COO of Vela Laboratories and responsible for analytical operations.
Jelena Novakovic	**Galenika AD, Novi Bedegrad, Serbia** Deputy Head of Microbiology in Quality Control.
Dr Patrik Petersson	**Novo Nordisk, Denmark** Principal Specialist focusing on chromatography and Quality by Design for analytical methods.
Dr Klaus Reif	**PhytoLab, Vestenbergsgreuth** Head of the Method Development Department.
Stephanie Richard	**Sanofi Pasteur, Marcy l'Etoile, France** Associate Scientist ARD EU Immunology.
Dr Michael Rieth	**Merck KGaA, Darmstadt, Germany** Head of Microbiological Quality Control of the Pharmaceutical Production.
Dr Markus Roucka	**Vela Laboratories, Vienna, Austria** Head of Laboratory, Dept. Assay Development.
Dr Jochen Scher	**Boehringer Ingelheim, Biberach** Principal scientist in the Analytical Development.
Dr Ralf Schröder	**Waters GmbH, Frechen, Germany** Laboratory Informatics department.
Don Singer	**GSK, Collegeville, USA** Global Lead Manager Microbiological Quality Research and Development.
Dr Ingo Spreitzer	**Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines, Langen, Germany** Deputy Section of Microbial Safety.
Dr Nigel Stapleton	**Microsafe Laboratories, Leiden, Netherlands** Managing Director.
Dr Helge F. Tippmann	**ALK-Abelló** Team Leader in QC Development, Global Product Development.
Christian Vogt	**Novartis Pharma AG, Basel, Switzerland** Head Biological & Microbiological Services Chemical Operations.
Dr Christine Weiß	**Labor L+S AG, Bad Bocklet, Germany** Section Head Microbiological and Biological Quality Testing.
Dr Robert Weiss	**Baxter, Vienna, Austria** Quality Control Coagulation.
Dr Friedrich von Wintzingerode	**Roche Diagnostics Gmbh Penzberg, Germany** Group Leader Microbiological IPC and Analytics for Release.

ECA – Trends in Chromatography (HPLC/UHPLC)

Analytics

New Stationary Phases in HPLC/UHPLC
➲ Dr Klaus Reif, PhytoLab, Vestenbergsgreuth

HPLC Method Development in Early-Stage Analytical Development
➲ Dr Jochen Scher, Boehringer Ingelheim, Biberach

Modelling of analytical (U)HPLC: an Important Element in the QbD Toolbox
➲ Dr Patrik Petersson, Novo Nordisk, Denmark

Transfer from HPLC to UHPLC: What can go Wrong and How to Avoid Problems
➲ Dr Patrik Petersson, Novo Nordisk, Denmark

The Application of LC-MS(MS) and HRMS in the Quality Control of Plant based Products
➲ Dr Klaus Reif, PhytoLab, Vestenbergsgreuth

Divers Hyphenated Separation Techniques in SME R&D-real life cases
➲ Dr Joanna Mania, DADA Consultancy, BV, NL

Use of HPLC-Mass spectrometry in Biosimilar Comparability Exercise
➲ Martin Blüggel, CBO, Protagen Protein Services GmbH

Image: BSL BIOSERVICE

ECA – Bioassays

Bioanalytics

Regulatory Expectations
➲ Dr Steffen Groß, Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines

Detection and „characterization" of Anti-Drug Antibodies with SPR technology
➲ Dr Markus Roucka, Vela Laboratories, Vienna, Austria

Trends and Challenges associated with cell based potency assays used in quality control applications
➲ Dr Ulrike Herbrand, Charles River Biopharmaceutical Services GmbH, Erkrath, Germany

Potency Assays for Coagulation Products
➲ Dr Robert Weiss, Baxter, Vienna, Austria

GLP Validation of Immunoassays for GLP Bioanalytics
➲ Dr Christoph Höppner, BSL Bioservice Scientific Laboratories, Munich, Germany

Biological assays for the assessment of antibody mediated cytotoxicity
➲ Dr Andreas Nechansky, Vela Laboratories, Vienna, Austria

Importance of Orthogonal Methods in the Analysis of Protein Aggregation: Case Studies
➲ Prof. Tudor Arvinte, Ph.D., Professor, Department of Biopharmaceutics, University of Geneva, Switzerland, CEO, Therapeomic Inc.

ECA – Current Developments and Trends in Sterility Testing

Microbiology

Pharmacopoeial Requirements – EP, USP, JP
➲ Dr Bettina Lauer, Vetter Pharma Fertigung GmbH & Co. KG, Ravensburg, Germany

Comparison Isolator vs. Cleanroom
➲ Dr Timo Krebsbach, Labor L+S AG, Bad Bocklet, Germany

Microbiology in Testing Isolators
➲ Christian Vogt, Novartis Pharma AG, Basel, Switzerland

Risk of microbiological cross contamination during the simultaneous testing of two different products in a two operator isolator
➲ Cyril Mounier, Getinge Life Sciences, Vendome, France

Rapid Sterility Methods
➲ Dr Rajesh K. Gupta, Consultant Vaccinologist & Microbiologist, former FDA

Automating the Compendial Sterility Test
➲ Dr David Jones, Rapid Micro Biosystems, Bedford, USA

Applicability and Validation of Rapid Microbiological Methods
➲ Peter Cornelis, Toxikon Europe NV, Leuven, Belgium

Avoid Observations for Sterility Testing
➲ Dr Bettina Lauer, Vetter Pharma Fertigung GmbH & Co. KG, Ravensburg, Germany

ECA – Laboratory Informatics – Update 2013

Analytics

Similarities, Differences and Potential of Different Applications like LIMS, ELN, SDMS, PLM, ERP, etc.
➲ Peter J. Boogaard, Industrial Lab Automation, Netherlands

Regulatory Requirements (European Perspective)
➲ Karl Heinz Menges, RP Darmstadt, Germany

Practical Handling of COTS Laboratory Computerised Systems
➲ Ulla Bondegaard, Novo Nordisk, Denmark

Implementation and Validation of LIMS Systems - a risk-based Approach
➲ Dr Helge F. Tippmann, ALK-Abelló

LIMS – 10 Years Paperless
➲ Dr Dirk Badura, CarbogenAmcis, Switzerland

The Paperless Lab - A Way into Process Optimization
➲ Peter J. Boogaard, Industrial Lab Automation, Netherlands

ELN - Implementation in an Established Labinformatics Landscape
➲ Dr Ralf Schröder, Waters GmbH, Frechen, Germany

ECA – Endotoxin and Pyrogen Testing

Microbiology

Developments in Regulatory Requirements
➲ Dr Ingo Spreitzer, Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines, Langen, Germany

Comparison of Pyrogen Test, LAL and MAT
➲ Dr Jürgen Balles, Labor L+S AG, Bad Bocklet , Germany

Assays for Glucans
➲ Dr Michael Rieth, Merck KGaA, Darmstadt, Germany

Case study: non conformity during the initial validation of vial depyrogenation by multiple rinsing
➲ Dr Olivier Chancel, Merial, Toulouse, France

Protein Masking - a critical limitation of LAL
➲ Dr Friedrich von Wintzingerode, Roche Diagnostics Gmbh Penzberg, Germany

Monocyte Activation Test: Assessment of several monocyte sources for the replacement of rabbit pyrogen test for inactivated bacterial vaccine control
➲ Stephanie Richard, Sanofi Pasteur, Marcy l'Etoile, France

Pyrogen testing by MAT (Monocyte Activation Test) using the human Monocyte cell line Mono Mac 6
➲ Dr Anja Fritsch, Confarma France, SARL, Homburg, France

Assuring Product Quality – In-Process Testing for Endotoxin
➲ Michael E. Dawson, Ph.D., RAC, Associates of Cape Cod, Inc.

Image: Vela Labs

ECA – Microbial Safety of Raw Materials and Excipients

Microbiology

Testing of Raw Materials – EP 2.6.12 and 2.6.13.
➲ Dr Marcel Goverde, MGP Consulting

Are Pharmacopeial Monograph Criteria Sufficient for Raw Material Specifications?
➲ Don Singer, GSK, Collegeville, USA

Environmental Conditions Impact on Quality of Raw Materials
➲ Jelena Novakovic, Galenika AD, Novi Bedegrad, Serbia

Testing of Raw Materials for Phytopharmaka
➲ Dr Cornelia Bodinet, Schaper – Brümmer, Salzgitter, Germany

Raw Materials and Excipients: The Basis for High Quality Products
➲ Dr Christine Weiß, Labor L+S AG, Bad Bocklet, Germany

Importance of a Quality Relationship with a Raw Material Supplier – Industrial Point of View
➲ Don Singer, GSK, Collegeville, USA

How to get the Most out of your CRO
➲ Dr Nigel Stapleton, Microsafe Laboratories, Netherlands

A growth based Rapid Method for fast detection of microbiological contamination
➲ Dr Mauro Anglana, Merck Millipore, Vimodrone, Italy

Easy Registration

Registration Form:
CONCEPT HEIDELBERG
Rischerstraße 8
69123 Heidelberg

Registration Form:
(06221) 84 44 34

E-Mail:
info@concept-heidelberg.de

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

Registration Options PharmaLab 2013

☐ Attending the PharmaLab Conferences – One Day Ticket for € 690,-

☐ Attending the PharmaLab Conferences – Two Days Ticket for € 1.190,-

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 (13 November 2013)** and I'm primarily interested in the conference:
- ☐ ECA – Trends in Chromatography (HPLC/UHPLC)
- ☐ ECA – Bioassays
- ☐ ECA – Current Developments and Trends in Sterility Testing

☐ I would also like to take part in the Social Event on the evening of 13 November.

☐ I would like to attend on **day 2 (14 November 2013)** and I'm primarily interested in the conference:
- ☐ ECA – Laboratory Informatics – Update 2013
- ☐ ECA – Endotoxin and Pyrogen Testing
- ☐ ECA – Microbial Safety of Raw Materials and Excipients

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.

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Reservation Form (Please complete in full)

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