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**PharmaLab 2015**
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# Rapid Microbiological Methods
# Adventitious Agents – Impurities and Contaminants
# Endotoxin and Pyrogen Testing

## Düsseldorf/Neuss, Germany
## 10-11 November 2015

### HIGHLIGHTS:

**Rapid Microbiological Methods**
- News from European Pharmacopoeia
- SILVA & ARB: high quality ribosomal RNA gene databases and services
- Modern Microbiological Safety Concepts – A Regulator's View on Cell-based Products
- Methods Validation
- Rapid Enumeration - MuScan

**Adventitious Agents – Impurities and Contaminants**
- Regulatory Perspectives and Expectations
- Modern Methods and Challenges
- Selecting and Validation Strategy for a Rapid Mycoplasma Detection Method
- Experiences with Alternative Testing according to EP
- Mycoplasma qPCR

**Endotoxin and Pyrogen Testing**
- News on European Pharmacopoeia
- Low Endotoxin Recovery
  - Regulatory Point of View
  - Observation of LPS aggregation change via atomic force microscopy (AFM) and dynamic light scattering (DLS)
  - Overcoming Strategies
- Recombinant Factors
- LAL Optimising

### AUTHORITY SPEAKERS:

**PATRICIA HUGHES, PH.D.**
FDA, USA
**JAN-OLIVER KARO**
German Agency for Vaccines and Biomedicines, Germany
**DR MANUELA LEITNER**
AGES – Austrian Agency for Health and Food Safety
**DR INGO SPREITZER**
German Agency for Vaccines and Biomedicines, Germany
Speaker from **EDQM**

### INDUSTRY SPEAKERS:

**DR FATMA GÖKŞIN BAHAR**
Arven Pharmaceuticals, Turkey
**DR PETER CORNELIS**
Toxikon Europe, Belgium
**STEFAN GÄRTNER**
Labor L+S, Germany
**PROF FRANK OLIVER GLÖCKNER**
Max Planck Institut & Jacobs University, Bremen, Germany
**DR RAJESH GUPTA**
Biologics Quality & Regulatory Consultants, USA
**ELENA GUSTCHINA**
Lonza, USA
**PETER HUONKER**
Zimmer, Austria
**DR PIETA IJZERMAN-BOON**
MSD, The Netherlands
**DR MARC KELLY**
MiCRA-Biodiagnostics, Institute of Technology Tallaght, Dublin, Ireland
**ROBERT MELLO, PH.D.**
Mello PharmAssociates, USA
**ANNA MILLS**
Rapid Micro Biosystems, UK
**DR JELENA NOVAKOVIC JOVANOVIC**
Galenika, Serbia
**MATTHEW PAQUETTE**
Pfizer Biotech, USA
**DR FRANCE AUDREY PELTIER**
Merck Millipore, Germany
**DR KENT PERSSON**
Octapharma, Sweden
**JOHANNES REICH**
University Regensburg, Germany
**PROF DR RENATE ROSENGARTEN**
Mycoplasma Biosafety Services, Austria
**JAN JAAP SCHOT**
MSD, The Netherlands
**HENRIK SALLING**
Novo Nordisk, Denmark
**DR MASAKAZU TSUCHIYA**
Cahrles River Laboratories, USA
**DR ASTRID VISSER**
Sanquin Plasma Products, The Netherlands
**HELENA WINDSOR**
Mycoplasma Experience
**DR FRIEDRICH VON WINTZINGERODE**
Roche Diagnostics, Germany

# Rapid Microbiological Methods

## Objectives

This conference offers you a unique possibility to evaluate the new developments in RMM systems to extend the experiences in validation as well as implementation of these systems in pharmaceutical industry. Furthermore you will learn more about the expectations of authorities and developments in regulatory requirements. Amongst this, experts from laboratory and industry will give an insight view in the routine use of RMM.

## Background

Microbial contamination poses enormous risks to pharmaceuticals and their consumers. To minimize the quality and financial risk, pharmaceutical and biopharmaceutical manufacturers collect thousands of samples for bioburden or sterility testing a year. The classic culture methods are often laborious and require long incubation times. In the field of some biopharmaceuticals, Advanced Therapy Medicinal Products and other modern products, it is often not possible to wait 7 or more days for a result. RMMs provide the ability to reduce time and costs for microbial detection and increase the safety level of the products.

In the meantime several new systems for the detection of microbial contaminants and new identification systems are available at the market or in validation. The regulatory authorities like FDA, EDQM or MHRA assist the implementation of RMMs e.g. with the revision of the related guidelines or pharmacopoeias.

## Moderator

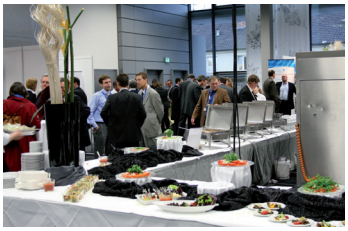
Dr Sven Deutschmann, *Roche Diagnostics, Penzberg, Germany and Chairman ECA Rapid Microbiological Methods Interest Group*

## Target Audience

This conference is of interest to professionals in Quality, Microbiology and Validation from

- Pharmaceuticals and Biopharmaceutical Companies
- Contract Service and Research Laboratories
- Government Agencies
- Cell Culture Collections

## Social Event



On the evening of the first congress day, on 10 November 2015, 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.

## Speakers

**PROF FRANK OLIVER GLÖCKNER,** *Max Planck Institut and Jacobs University, Bremen, Germany*
Head of Microbial Genomics and Bioinformatics Research Group.

**DR RAJESH GUPTA,** *Biologics Quality & Regulatory Consultants, LLC, USA*
Co-Owner and Principal Consultant; formerly Deputy Division Director and Lab Chief, Div of Product Quality (Div of Biological Standards & QC) FDA.

**PETER HUONKER,** *Zimmer GmbH, Winterthur, Switzerland*
Manager Microbial Services.

**DR PIETA IJZERMAN-BOON,** *MSD, The Netherlands*
Associate Director Quantitative Sciences/Center for Mathematical Sciences-Europe.

**JAN-OLIVER KARO,** *Paul Ehrlich Institut, German Agency for Vaccines and Biomedicines, Germany*
Scientist Section 1/3 Microbial Safety.

**ANNA MILLS,** *Rapid Micro Biosystems, UK*
Senior Field Application Specialist

**DR MARC KELLY,** *MiCRA-Biodiagnostics, Institute of Technology Tallaght, Dublin, Ireland*
Senior Scientist on Development of Process Sensors for Bacterial Contamination.

**JAN JAAP SCHOT,** *MSD, The Netherlands*
Specialist Microbiology for Manufacturing & Quality / Center of Expertise Microbiology.

**SPEAKER COUNCIL OF EUROPE -** *EDQM & Healthcare, Strassbourg, France*
European Pharmacopoeia Department.

## Programme

**SILVA & ARB: high quality ribosomal RNA gene databases and services**

- Ribosomal RNA: the universal marker gene
- Behind the scenes: curating alignments and taxonomy
- Services: databases, primer & probe evaluation, analysis of high-throughput sequencing data
- Applications: biodiversity, phylogeny and microbial identification

PROF FRANK OLIVER GLÖCKNER, *Max Planck Institut & Jacobs University Bremen*

**Revision of European Pharmacopoeia Chapter 5.1.6**

- Reasons for revision
- Status of the Pharmeuropa enquiry
- Next steps

SPEAKER, EDQM

**MICROPRINT BIOCARD: Imprinted Polymer Technology for the Rapid Detection of Microorganisms**

- Development of cell-selective imprinted polymers with integrated electrodes systems.
- Validation of a cell-capture process for Escherichia coli enumeration.
- Opportunities for the MiCROPRINT BIOCARD in Pharmaceutical manufacture

DR MARC KELLY, *MiCRA-Biodiagnostics, Institute of Technology Tallaght*

**Validation of a Sterility Test**

- New Sterility Test System
- Validation Strategy
- Use of Comparability Protocol to optimise acceptance

ANNA MILLS, *Rapid Micro Biosystems*

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**Rapid Enumeration with MU-scan: Risk or Improvement**

- Method development
- Limitations and benefits
- Statistical model for enumeration
- Recognition of false positives
- Comparison with compendial method
- Consequences for validation

JAN JAAP SCHOT/ DR PIETA IJZERMAN-BOON, *MSD*

**Modern Microbiological Safety Concepts – A Regulator's View on Cell-based Products**

- Microbiological challenges and new safety concepts
- Emerging issues and regulatory aspects in the field of cell-based products
- The impact of rapid methods – Need for a paradigm change?

JAN-OLIVER KARO, *Paul-Ehrlich-Institut, German Agency for Vaccines and Biomedicines*

**Approaches for Validation of Rapid Sterility Testing Methods**

- Validation - Suitable for Intended Purpose
- Limit of Detection
- Specificity
- Equivalency

DR RAJESH GUPTA, *Biologics Quality & Regulatory Consultants*

**Identification with MALDI-TOF**

- Choice of the system
- Implementation
- Validation

PETER HUONKER, *Zimmer*

# Adventitious Agents – Impurities and Contaminants

## Objectives

This Conference will provide an opportunity to reinforce and expand your knowledge of the special area of impurities of biological origin and contaminants in biopharmaceutical entities from initial development to the market with emphasis on

- Detection, profiling and control in drug substances, intermediates and drug products
- Practical aspects of method validation for determination
- Testing for contamination of mycoplasma or viruses

## Background

ICH Topic Q 6 B respectively the Note For Guidance On Specifications: Test Procedures And Acceptance Criteria For Biotechnological/Biological Products (CPMP/ICH/365/96) states related to Impurities and Contaminants:

"Impurities
In addition to evaluating the purity of the drug substance and drug product,.... the manufacturer should also assess impurities, which may be present. Impurities may be either process or product-related. They can be of known structure, partially characterised, or unidentified. When adequate quantities of impurities can be generated, these materials should be characterised to the extent possible and, where possible, their biological activities should be evaluated.

Process-related impurities ... i.e., cell substrates (e.g., host cell proteins, host cell DNA), cell culture (e.g., inducers, antibiotics, or media components), or downstream processing product-related impurities (e.g., precursors, certain degradation products) are molecular variants arising during manufacture and/or storage, which do not have properties comparable to those of the desired product with respect to activity, efficacy, and safety. ....

Contaminants
Contaminants in a product include all adventitiously introduced materials not intended to be part of the manufacturing process, such as chemical and biochemical materials (e.g., microbial proteases), and/or microbial species. Contaminants should be strictly avoided and/or suitably controlled with appropriate in-process acceptance criteria or action limits for drug substance or drug product specifications (section 2.3). For the special case of adventitious viral or mycoplasma contamination, the concept of action limits is not applicable, and the strategies proposed in ICH Harmonised Tripartite Guidelines "Quality of Biotechnological/Biological Products: Viral Safety Evaluation of Biotechnology Derived Products Derived from Cell Lines of Human or Animal Origin" and "Quality of Biotechnological/Biological Products: Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products" should be considered."

Therefore, it is indispensable for manufacturers of drug substances and drug products of biological origin, to establish suitable detection systems for such adventitious agents.

## Moderator

Dr Sven Deutschmann, *Roche Diagnostics, Penzberg, Germany and Chairman ECA Rapid Microbiological Methods Interest Group*

## Target Audience

The conference addresses all personnel involved in development of drug substances and drug products from scientific staff to laboratory heads involved in R&D. The needs of Laboratory Managers, Supervisors and Analysts in pharmaceutical quality assurance and quality control departments will also be covered.

## Programme

**Viral safety in biologicals – The regulatory perspective**

- General Aspects
- Relevant process steps
- Validation design and studies
- Regulatory framework

**DR MANUELA LEITNER,** *AGES – Austrian Agency for Health and Food Safety*

**Challenges in Testing for Adventitious Agents during Manufacture of Biological Products**

- Scientific Aspects of Adventitious Agents Testing
- Regulations and Guidance
- Building Safety & Quality During Manufacture
- Modern Methods and Challenges

**DR RAJESH GUPTA,** *Biologics Quality & Regulatory Consultants*

**Mycoplasma – Standards and Validation**

**PROF DR RENATE ROSENGARTEN,** *Mycoplasma Biosafety Services*

**Selecting a rapid mycoplasma assay supporting recombinant production**

- Selection criteria
- Validation strategy and process
- Pitfalls and practical experiences

**DR KENT PERSSON,** *Octapharma*

**Dive into traditional Mycoplasma culture method**

- Mycoplasma testing workflow
- Media complexity
- Quality Control

**DR FRANCE AUDREY PELTIER,** *Merck Millipore*

**PCR - Complementing Culture Expertise - The introduction of PCR into a culture based laboratory**

- The drivers for investment in PCR Technology
- Introduction of PCR across research and QC functions
- EP NAT Compliance - the reality for SMEs
- Development of a hybrid test

**HELENA WINDSOR,** *Mycoplasma Experience*

**Experiences with in-house qPCR assay for Mycoplasma detection**

- Presentation of in-house assay
- New results using the novel Mycoplasma Bioballs for matrix spiking
- New results from direct qPCR (time reduced to hours)
- Pros and cons regarding both direct and the hybrid approach
- Validation setup
- New results from direct qPCR (time reduced to hours)
- Pros and cons regarding both direct and the hybrid approach
- Validation setup

**HENRIK SALLING,** *Novo Nordisk*

## Speakers

**DR RAJESH GUPTA,** *Biologics Quality & Regulatory Consultants, LLC, USA*
Co-Owner and Principal Consultant; formerly Deputy Division Director and Lab Chief, Div of Product Quality (Div of Biological Standards & QC) FDA.

**DR MANUELA LEITNER,** *AGES, Austrian Agency for Health and Food Safety*
Quality Assessor for Biopharmaceuticals and Plasma Master File.

**DR FRANCE AUDREY PELTIER,** *Merck Millipore, Germany*
Product Manager Mycoplasma Media.

**DR KENT PERSSON,** *Octapharma AB, Stockholm,, Sweden*
Project Manager, PCR Department.

**PROF DR RENATE ROSENGARTEN,** *Mycoplasma Biosafety Services GmbH*
Managing Director | COO, CSO, BioTech Center.

**HENRIK SALLING,** *Novo Nordisk, Denmark*
Development Scientist, Biopharm Downstream Development & Virology.

**HELENA WINDSOR,** *Mycoplasma Experience*

# Endotoxin and Pyrogen Testing

## Objectives

This Conference will inform you about current developments in Endotoxin and Pyrogen testing as well as the practical use of established test methods like LAL for Endotoxin testing,

You become informed about
- International regulatory developments
- Feasibility of new and innovative products and methods.
- Special issues like masking/LER
- Testing of critical substances
- Application of alternative testing methods – MAT or RFC

## Background

Testing for Endotoxins and Pyrogens is a critical in-process and final release test for parenteral products. Different approaches have been developed over the last few decades to provide solutions for the breadth of product range that is tested for endotoxins and pyrogens: RPT, LAL, MAT. With the LAL test method as the established, compendial methodology for bacterial endotoxins with harmonization of the EP, USP and JP. Due to the importance of these tests, they are under ongoing scrutiny by industry and regulators to ensure testing efficacy and safe manufacturing and release of products into the market.

Novel advanced medicinal products as well as complex biopharma formulations pose testing challenges and require in-depth knowledge and expertise in the field of Endotoxins and Pyrogens.

In addition, as the choice of solutions offered by suppliers for endotoxin testing becomes wider (e.g. recombinant factor C, ELISA-based test kits, automated LAL cartridge technology) it is important to get a data driven understanding of the advantages and limitations of each approach.

Current discussions on low endotoxin recovery and endotoxin masking and the need for future innovations within BET that provide solutions to current challenges will be presented. These examples show the need for staying abreast of scientific developments.

## Moderator

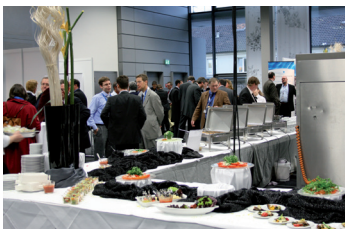
Dr Friedrich von Wintzingerode, *Roche Diagnostics*

## Target Audience

This Conference is addressed to all persons of
- pharmaceutical manufacturers
- biopharmaceutical companies
- contract laboratories
- tissue establishments

who are involved in Endotoxin and Pyrogen Testing or must evaluate the risks for release.

## Social Event



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## Programme

### The Limulus Amebocyte Lysate (LAL) Test for Bacterial Endotoxins Discovery, Development and Applications

- Discovery,
- Development
- Applications

Key Note

**JACK LEVIN, M.D.,** *University of California, School of Medicine*

### Current Developments in Endotoxin / Pyrogen testing in the European and other Pharmacopeias

- Introduction : Legal situation Europe compared to US
- Ph. Eur: Reasons and Details for current changes and challenges
  - European Pharmacopeia policy on bacterial endotoxins in substances for pharmaceutical use
  - Guidelines for using the test for bacterial endotoxins 5.1.10
  - Pyrogens 2.6.8.
  - Monocyte activation test (2.6.30.)
- FDA / USP
  - 2012 FDA „Guidance for Industry: Pyrogen and Endotoxins testing
  - USP
- Chinese Pharmacopeia

**DR INGO SPREITZER,** *Paul-Ehrlich-Institut, Germany Agency for Vaccines and Biomedicines*

### Kinetic Bacterial Endotoxin Assay Challenges for Biologics

- Method Validation
- Challenges

**DR FATMA GÖKŞIN BAHAR,** *Arven Pharmaceuticals*

### Increasing LAL Testing Efficiency with Endosafe® Nexus™ Robotic Endotoxin Testing System

- Classical Issues with Large Number of Samples
  - multiple Analysts
  - multiple Cartridge Systems
- Advantages of Robotic Testing System
  - Sample Organisation Software
  - Test Performance
  - Data Interpretation and Reporting

**MATTHEW PAQUETTE,** *Pfizer Biotech*

### An Improved Monocyte Activation Test Using Cryopreserved Pooled Human Mononuclear Cells

- Comparing Sensitivity
- Reproducibility
- Comparing Results of MAT,RPT and BET Testing

**DR ASTRID VISSER,** *Sanquin Plasma Products*

### Challenges on Performing LAL in Oil Products

- Background of endotoxin examinations.
- Overview of pharmacopoieal bacterial endotoxin tests.
- Sample preparation of oil products, example.
- Method validation for chosen oil product, example.
- Demands, rational thinking and scientific base- solution for every problem

**DR JELANA NOVAKOVIC JOVANOVIC,** *Galenika*

### Pyrogen and Endotoxin Analysis: Concepts and Considerations As We Move Forward

- Historical Assays and the Rise of Biologic Parenteral Formulations
- LER/LLR/Masking
- Knowledge Based Considerations for Process and Product
  - Clinical trial data collection
  - Formulation Development
  - Analytical Methods – Single assays vs. Body of Evidence

**ROBERT MELLO, PH.D.,** *Mello PharmAssociates*

### LPS Aggregation Changes in Low Endotoxin Recovery –Seeing is believing

- Direct observation of LPS aggregation by using high speed atomic force microscopy (HSAFM)
- Observation of LPS aggregation change in Low Endotoxin Recovery
- Overall observation of LPS aggregation change by dynamic light scattering (DLS)

**DR MASAKAZU TSUCHIYA,** *Charles River Laboratories*

## Programme

**Everything You Always Wanted to Know About Endotoxin, But Were Afraid to Ask**


- Understand the mode of action on a molecular level
- Endotoxin structure-function relationship.
- LPS – understanding the biomedical toxicity and new strategies to handle it

**PROF. ULRICH ZÄHRINGER,** *Forschungszentrum Borstel*

**FDAs Current Thinking on LER**

- Overview of biotech drug approvals
- Regulatory challenges: known and unknowns
- LER and path forward for biotech drug approval

**DR PATRICIA HUGHES,** *CDER, FDA*

**Case Study: Overcoming Endotoxin Masking in a Drug Product**

- Summary of demasking workflow
- Cause analysis of low endotoxin recovery
- Development of a suitable sample preparation protocol for demasking of endotoxins
- Validation of the dedicated demasking approach

**JOHANNES REICH,** *University Regensburg*

**Endotoxin Masking – Origin, Natural Occuring Endotoxins and Demasking**

- Origin of masking.
- Natural Occurring Endotoxins and there effect on masking.
- The effect of the structure of endotoxins on masking.
- Demasking attempts using the LAL assay and the Monocyte Activation assay

**PETER CORNELIS,** *Toxikon Europe*

**Development of a LAL-based method to overcome LER in a Biologics product**

- General aspects of LER and other endotoxin masking effects.
- Method development and validation
- Outlook

**DR FRIEDRICH V. WINTZINGERODE,** *Roche Diagnostics*

**Recombinant Factor C : Sustainable Alternative for Endotoxin Detection**

- Possibilities for Improvement
- Alternative Testing Products and Platforms

**ELENA GUSTCHINA,** *Lonza*

**Reduction of Test-Interferences by Using a Recombinant Limulus Factor c ELISA**

- Background of endotoxin test interference
- Advantages of rFC-ELISA
- Possible applications

**STEFAN GÄRTNER,** *Labor L+S*

**MAT testing with Cell Lines**

**DR ANJA FRITSCH,** *Confarma France*

## Speakers

**DR FATMA GÖKŞIN BAHAR,** *Arven Pharmaceuticals, Turkey*
Biotechnology Quality Control Specialist.

**PETER CORNELIS,** *Toxikon Europe NV, Leuven, Belgium*
Department Supervisor Microbiology & In Vitro Toxicology.

**DR. ANJA FRITSCH,** *Confarma France Sarl, Molecular Biology*
Chief Scientific Officer.

**STEFAN GÄRTNER,** *Labor L+S AG, Germany*
Head Special Department Testing of Sterile Products.

**ELENA GUSTCHINA,** *Lonza, USA*
Scientist, Enzyme and Protein Chemistry, Assay and Process Development.

**PATRICIA HUGHES, PH.D.,** *U.S. Food and Drug Administration*
Branch Chief (Actg), Division of Microbiology Assessment, OPF/ OPQ/ CDER.

**ROBERT J. MELLO, PH.D.** *Mello PharmAssociates, LLC, USA*
Former Senior Microbiology Reviewer, New Drug Microbiology Staff, FDA.

**DR JELENA NOVAKOVIC JOVANOVIC,** *Galenika AD, Serbia*
Deputy Head of Microbiology in QC Sterile and Non Sterile Products.

**MATTHEW PAQUETTE,** *Pfizer Biotech, USA*
Quality Control Scientist II in Microbiology.

**JOHANNES REICH,** *University Regensburg, Germany*
PhD Student wit focus on the aggregation and interaction of Lipopolysaccharides as well as the related activities in limulus based detection systems.

**DR INGO SPREITZER,** *Paul-Ehrlich-Institut, Germany Agency for Vaccines and Biomedicines, Langen, Germany*
Deputy Section of Microbial Safety.

**DR MASAKAZU TSUCHIYA,** *Charles River Laboratories, USA*
Senior Research Scientist in Endotoxin and Microbial Detection.

**DR ASTRID VISSER,** *Sanquin Plasma Products, The Netherlands*
Business Development Manager, Project Leader MAT Testing.

**DR FRIEDRICH VON WINTZINGERODE,** *Roche Diagnostics GmbH, Penzberg, Germany*
Senior Manager QC Microbiology. Lead of Endotoxin Expert Group Roche/Genentech.

**PROF. ULRICH ZÄHRINGER,** *Research Center Borstel, Germany*

# Agenda

| Time | Rapid Microbiological Methods<br>Tuesday, 10 November 2015 | Adventitious Agents<br>Wednesday,<br>11 November 2015 | Endotoxin and Pyrogen Testing<br>Tuesday/Wednesday, 10/11 November 2015 | | Time |
|---|---|---|---|---|---|
| 9.00 h | Welcome and Introduction | Welcome and Introduction | Welcome and Introduction | Everything You Always Wanted to Know About Endotoxin, But Were Afraid to Ask<br>*Prof. Ulrich Zähringer, Forschungszentrum Borstel* | 9.00 h |
| 9:15 h | SILVA & ARB: high quality ribosomal RNA gene databases and services<br>*Prof Frank Oliver Glöckner, Max Planck Institut & Jacobs Univserity Bremen* | Viral Safety for Biologicals<br>*Dr Manuela Leitner, AGES – Austrian Agency for Health and Food Safety* | The Limulus Amebocyte Lysate (LAL) Test for Bacterial Endotoxins: Discovery, Development and Applications<br>*Jack Levin, M.D. University of California School of Medicine* | | 9:15 h |
| 9.30 h | | | | FDAs Current Thinking on LER<br>*Dr Patricia Hughes, CDER, FDA* | 9.30 h |
| 9:45 h | | | | | 9:45 h |
| 10.00 h | Revision of Chapter 5.1.6.<br>*Speaker , EDQM* | Challenges in testing for Adventitious Agents during Manufacture of Biological Products<br>*Dr Rajesh Gupta, Biologics Quality & Regulatory Consultants* | Current Developments in Endotoxin / Pyrogen testing in the European and other Pharmacopeia<br>*Dr Ingo Spreitzer, Paul-Ehrlich-Institut; German Agency for Vaccines and Biomedicines* | | 10.00 h |
| 10:15 h | | | | Break<br>*(Take advantage of the break to visit the exhibition)* | 10:15 h |
| 10.30 h | | | | | 10.30 h |
| 10:45 h | Break<br>*(Take advantage of the break to visit the exhibition)* | Break<br>*(Take advantage of the break to visit the exhibition)* | Break<br>*(Take advantage of the break to visit the exhibition)* | | 10:45 h |
| 11.00 h | | | | Case Study: Overcoming Endotoxin Masking in a Drug Product<br>*Johannes Reich, University Regensburg* | 11.00 h |
| 11:15 h | | | | | 11:15 h |
| 11.30 h | MICROPRINT BIOCARD: Imprinted Polymer Technology for the Rapid Detection of Microorganisms<br>*Dr Marc Kelly, MiCRA-Biodiagnostics, IIT* | Mycoplasma – Standards and Validation<br>*Prof Dr Renate Rosengarten, Mycoplasma Biosafety Services* | Kinetic Bacterial Endotoxin Assay Challenges for Biologics<br>*Dr Fatma Gökşin Bahar, Arven Pharmaceuticals* | | 11.30 h |
| 11:45 h | | | | Endotoxin Masking – Origin, Natural Occuring Endotoxins and Demasking<br>*Peter Cornelis, Toxikon Europe* | 11:45 h |
| 12.00 h | Validation of a Sterility Test<br>*Anna Mills, Rapid Micro Biosystems* | | | | 12.00 h |
| 12:15 h | | | | | 12:15 h |
| 12.30 h | Rapid Enumeration with MuScan: Risk or Improvement?<br>*Jan Jaap Schot/Dr Pieta IJzerman-Boon, MSD* | Selecting a rapid mycoplasma assay supporting recombinant production<br>*Dr Kent Persson, Octapharma* | Increasing LAL Testing Efficiency with Endosafe® Nexus™ Robotic Endotoxin Testing System<br>*Matthew Paquette, Pfizer Biotech* | Development of a LAL-based method to overcome LER in a Biologics product<br>*Dr Friedrich v. Wintzingerode, Roche Diagnostics* | 12.30 h |
| 12:45 h | | | | | 12:45 h |
| 13.00 h | Lunch Break<br>*(Take advantage of the break to visit the exhibition)* | Lunch Break<br>*(Take advantage of the break to visit the exhibition)* | Lunch Break<br>*(Take advantage of the break to visit the exhibition)* | | 13.00 h |
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| 13:45 h | | | | | 13:45 h |
| 14.00 h | | | | | 14.00 h |
| 14:15 h | | | | | 14:15 h |
| 14.30 h | Modern Microbiological Safety Concepts – A Regulator´s View on Cell-based Products<br>*Jan-Oliver Karo, Paul-Ehrlich-Institut, German Agency for Vaccines and Biomedicines* | Dive into traditional Mycoplasma culture method<br>*Dr France Audrey Peltier, Merck Millipore* | An Improved Monocyte Activation Test Using Cryopreserved Pooled Human Mononuclear Cells<br>*Dr Astrid Visser, Sanquin Plasma Products* | | 14.30 h |
| 14:45 h | | | | Recombinant Factor C : Sustainable Alternative for Endotoxin Detection<br>*Elena Gustchina, Lonza* | 14:45 h |
| 15.00 h | | | | | 15.00 h |
| 15:15 h | Break<br>*(Take advantage of the break to visit the exhibition)* | Break<br>*(Take advantage of the break to visit the exhibition)* | Break<br>*(Take advantage of the break to visit the exhibition)* | | 15:15 h |
| 15.30 h | | | | Break<br>*(Take advantage of the break to visit the exhibition)* | 15.30 h |
| 15:45 h | | | | | 15:45 h |
| 16.00 h | Approaches for Validation of Rapid Sterility Testing Methods<br>*Dr Rajesh Gupta, Biologics Quality & Regulatory Consultants* | Long-Term Experience regarding alternative mycoplasma testing according to EP<br>*Dr Thomas Hämmerle, Baxalta Innovations* | Challenges on Performing LAL in Oil Products<br>*Dr Jelena Novakovic Jovanovic, Galenika* | | 16.00 h |
| 16:15 h | | | | Reduction of Test-Interferences by Using a Recombinant Limulus Factor c ELISA<br>*Stefan Gärtner, Labor L+S* | 16:15 h |
| 16.30 h | | | Pyrogen and Endotoxin Analysis: Concepts and Considerations As We Move Forward<br>*Robert Mello, Ph.D., Mello PharmAssociates* | | 16.30 h |
| 16:45 h | Identification with MALDI-TOF<br>*Peter Huonker, Zimmer* | Experiences with in-house qPCR assay for Mycoplasma detection<br>*Henrik Salling, Novo Nordisk* | | | 16:45 h |
| 17.00 h | | | | MAT Testing with Cell Lines<br>*Dr Anja Fritsch, Confarma* | 17.00 h |
| 17:15 h | | | LPS Aggregation Changes in Low Endotoxin Recovery –Seeing is believing<br>*Dr Masakazu Tsuchiya, CRL* | | 17:15 h |
| 17.30 h | Final Discussion | Final Discussion | | Final Discussion | 17.30 h |
| 17:45 h | | | Discussion | | 17:45 h |
| 18:00 h | | | | | 18:00 h |

## Easy Registration

**Reservation Form:**
**CONCEPT HEIDELBERG**
**P.O. Box 10 17 64**
**69007 Heidelberg**
**Germany**

**Reservation Form:**
**+ 49 6221 84 44 34**

**e-mail:**
**info@concept-heidelberg.de**

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

### Dates
Tuesday, 10 November 2015, 09.00 – 18.00 h
Wednesday, 11 November 2015, 09.00 – 18.00 h
(Registration Monday, 9 November, 19.00 – 20.30 h and
Tuesday, 10 November/Wednesday, 11 November 08.00 – 09.00 h)

### Venue
Swissôtel Düsseldorf / Neuss
Rheinallee 1
D-41460 Neuss
Germany
Tel.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
Emailus@swissotel-duesseldorf.de

### Fees
EUR 690,- for one day ticket plus VAT
EUR 1.380,- for two days ticket plus VAT

The conference fee is payable in advance after receipt of invoice and includes lunch on that day/on both days as well as beverages during the event and during breaks. It also includes the Social Event on the evening of the first congress day (registration for 10 or 10&11 November 2015). VAT is reclaimable.

Your registration also entitles you to participate in all other PharmaLab Congress conferences during the day of your conference/during the two days. For information on all PharmaLab conferences please visit **www.pharmalab-congress.com**.

### Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.pharmalab-congress.com

### PLEASE NOTE
Please note that 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 (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center.

Please further note that there will be no room 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.

### Organisation & Contact
P.O. Box 10 17 64
D-69007 Heidelberg
Phone +49 (0) 62 21/84 44-0; Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de; www.concept-heidelberg.de

**For questions regarding content:**
Axel H Schroeder (Operations Director) at +49-6221/84 44 10, or per e-mail at schroeder@concept-heidelberg.de.
**For questions regarding reservation, hotel, organisation etc.:**
Mr Detlef Benesch (Organisation Manager) at +49-6221/84 44 45, or per e-mail at benesch@concept-heidelberg.de.

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If the bill-to-address deviates from the specification to the right, please fill out here:

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CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Reservation Form (Please complete in full) +49 6221 84 44 34

Part of PharmaLab 2015, Düsseldorf/Neuss, Germany, 10-11 November 2015
☐ 1-Day Ticket (10 or 11 Nov.) – € 690,- ☐ 2-Days Ticket (10 and 11 Nov.) – € 1.380,-
I would like to attend the following conference(s):
☐ **Rapid Microbiological Methods** (10 November 2015)
☐ **Adventitious Agents – Impurities and Contaminants** (11 November 2015)
☐ **Endotoxin and Pyrogen Testing** (10/11 November 2015)

☐ Yes, I will participate in the Social Event on 10 Nov. (for delegates on 10 or 10/11 Nov. 2015).
☐ Mr ☐ Ms

_____
Title, first name, surname

_____
Company

_____
Department

_____
**Important: Please indicate your company's VAT ID Number**

_____
**Please indicate the Purchase Order Number, if applicable**

_____
Street / P.O. Box

_____
City Zip Code Country

_____
Phone / Fax

_____
E-Mail (Please fill in)

**PLEASE NOTE:** Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice!

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 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)!

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/eca_privacy.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.

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