Endotoxin and Pyrogen Testing
Rapid Microbiological Methods
Microbial Safety of Raw Materials and Excipients

HIGHLIGHTS:
- **Rapid Microbiological Methods**
  - Regulatory Overview
  - Determination of Microbial Growth by Laser Absorption Spectroscopy
  - Rapid Sterility Test
  - Methods Validation
  - EM and Advanced Sampling
  - Container Closure Integrity Testing

- **Microbial Safety or Raw Materials and Excipients**
  - Regulatory Framework
  - Virus Safety Strategies
  - Strategies for Reduced Testing of Excipients
  - Risk Assessment
  - Water Testing and Biofilms

- **Endotoxin and Pyrogen Testing**
  - News on European Pharmacopoeia
  - FDA – Current Thinking
  - Low Endotoxin Recovery
    - Regulatory Point of View
    - Industrial LAL Experiences
    - Demasking Strategies
  - Current Way on RFC
  - MAT Experiences

8/9 November 2016, Düsseldorf/Neuss, Germany
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 into the routine use of RMM.

Background
Microbial contamination poses enormous risks to pharmaceuticals and their consumers. To minimize quality as well as financial risks, 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 Working 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 8 November 2016, 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
DAVID BRÜCKNER, F. Hoffmann-La Roche, Switzerland
Since 2014 he is PhD student at F. Hoffmann-La Roche in pharmaceutical sciences and QC microbiology, collaborating with University of Basel.

GILBERTO DALMASO, Particle Measuring Systems, Italy
Global Aseptic Processes Development Manager.

DR MICHAEL MILLER, Microbiology Consultants LLC, USA
Global thought leader and subject matter expert in rapid microbiological methods.

DR THOMAS MEINDL, Labor L+S AG, Germany

DR JEANNE MOLDENHAUER, Excellent Pharma Consulting, Inc.
Vice President Excellent Pharma Consulting and Director od Energy Concepts Inc.

DR DAVID ROESTI, Novartis Pharma Stein AG, Switzerland
Head of the RMM team and the Novartis Pharma expert network in microbiology.

DR RON SMITH, Janssen Pharmaceuticals
Ron is Director, Quality Assurance – External Supply Integration.
### Programme

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<td>Data Integrity Challenges for Analytical Labs</td>
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<td>Validation Strategy for Rapid Microbial Detection Celsis AMPiScreen</td>
<td><strong>DR RON SMITH</strong>, <em>Janssen Pharmaceuticals</em></td>
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</table>
Microbial Safety of Raw Materials and Excipients
9 November 2016, Düsseldorf/Neuss, Germany

Objectives

This conference is designed to provide you information of the pharmacopoeial requirements, possible issues with special substances, microbiological challenges and necessary tests during life cycle.

During this Conference we discuss:

- International regulatory requirements
- What should be tested
- Skip lot testing
- Specific pitfalls e.g. toxicity issues, inhomogenous distribution of contaminants
- Storing and retesting

Background

The quality of raw materials and excipients is one of the important factors for a suitable final product. With the implementation of the EU Directive 2001/83/EC into national law, all active pharmaceutical ingredients and the yet-to-be-defined Certain Excipients used in pharmaceutical manufacturing must be produced in compliance with current Good Manufacturing Practice (cGMP). As the current regulation is limited the legal enforceability is and will remain difficult. There is no Commission Directive on GMP for certain excipients for the time being and the preparation of such a Directive will not be continued as originally foreseen in Article 46(f) of Directive 2001/83/EC. However a series of recent incidents with tragic consequences for public health showed excipients of substandard quality to be involved and presents a global challenge for both the producer and user of pharmaceutical excipients. Against the background of the current situation the need of compulsory quality standards for manufacture and distribution of pharmaceutical excipients is quite obvious.

Moderator

Dr David Roesti, Novartis Pharma Stein, Switzerland

Target Audience

- Employees and senior staff of manufacturers of raw materials and excipients
- QA/QC microbiological laboratory staff
- Contract Laboratories
- Production and purchase departments

Speakers

**DR ANJA FRITSCH**, Conforama France SAS
Chief Scientific Officer.

**DR RALF KLEIN**, ViruSure GmbH, Vienna, Austria

**DR LAURENT LEBLANC**, bioMérieux, France
Pharmaceutical and Cosmetics Culture Media R&D Manager.

**DR MANUELA LEITNER**, AGES – Austrian Agency for Health and Food Safety
Quality Assessor for plasma derived Medicinal Products and Plasma Master File. Since 2008 she is an EMA expert.

**DR INGRID MECKLENBRÄUKER**, Novartis Pharma Stein, Switzerland
Joined Novartis Pharma Stein in 2013 as QC Lab Coordinator (Non-sterile Drug Products).

**DR JELENA NOVAKOVIC**, Galenika AD, Novi Bedegrad, Serbia
Deputy Head of Microbiology in Quality Control, working as microbiologist since 2008.

**CHRISTINE WEISS**, Labor L+S AG, Germany
Section Head Microbiological and Biological Quality Testing.
## Programme

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<thead>
<tr>
<th>Challenges for QC Networks</th>
<th>DR SVEN M. DEUTSCHMANN, Roche Diagnostics, Chairman ECA Pharmaceutical Microbiology Group</th>
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</table>
| Special materials in special products – biological excipients/raw materials in biopharmaceuticals | ■ Overview  
■ Active substance and excipients combinations  
■ Stability  
■ Regulatory framework  
DR MANUELA LEITNER, AGES – Austrian Agency for Health and Food Safety |
| Detection of pyrogenic contaminations in raw materials | ■ Regulatory background  
■ A risk-based approach to raw material testing  
■ Testing development for complex raw materials, case studies  
DR ANJA FRITSCH, Conforama France |
| Microbial quality of raw materials | ■ Importance of raw materials in pharmaceutical industry.  
■ Factors influencing microbial quality of raw materials.  
■ Should microbial quality of all raw materials be tested  
■ Authority recommendations for testing of raw materials.  
■ Suitability test for raw materials.  
■ Absence of which microorganisms should be tested and why?  
■ Demands, rational thinking and scientific base- solution for every problem.  
DR JELENA NOVAKOVIC, Galenika |
| Creating a culture of Data Integrity using an automated enumeration method | ■ Introduction of the Evisight Compact system and the high magnification technology  
■ Performance overview compared to manual reading (EM, filter)  
■ Future developments  
DR LAURENT LEBLANC, bioMérieux |
| Virus risk minimisation strategies for biopharmaceutical products | ■ Basic strategies for understanding and controlling virus risk  
■ Historical incidents of contamination in biopharmaceutical products  
■ Lessons learned in how best to control the risk  
DR RALF KLEIN, ViruSure |
| Reduced Testing of Excipients | ■ Microbiological Acceptance Criteria  
■ Classification  
■ Microbiological Characteristics  
■ Test Frequency  
■ OOE limits  
■ Examples  
DR INGRID MECKLENBRÄUKER, Novartis Pharma Stein |
| Microbiological Aspects of Water and Biofilms | ■ Microbiologica Aspects of Water  
■ Water Testing  
■ Biofilms in Watersystems  
CHRISTINE WEISS, Labor L+S |
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, Senior Manager QC Microbiology. Lead of Endotoxin Expert Group Roche/Genentech.

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

On the evening of the first congress day, on 8 November 2016, 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.
## Data Integrity Challenges for Analytical Labs

**Endotoxin Testing - from beginning to present**
- History of Testing
- Further Developments
- Current challenges

**FDA's Current Thinking on LER**
- Overview of biotech drug approvals
- Regulatory challenges: known and unknowns
- LER and path forward for biotech drug approval

**Spike/hold recovery study: a window to the mystery of LER**
- Study design principle
- Important process parameters
- Cause and effect relationship
- Where we go from here

**Case study: how to overcome BET validation of a product exhibiting complex interference patterns through describing a multi-step approach**
- Introduction to BET challenges and hot topics
- Overview of the range of interferences that can occur during testing
- Roadmap/List of options/solutions available
- Risk assessment and method development for accurate testing

**Biophysical investigations into the LER**
- Endotoxin aggregates
- Endotoxin size distribution
- Acyl chain melting
- Supramolecular conformation

**Correlations Between LER Formulation Excipients and LPS Structure**
- Challenges of characterizing biophysical properties of LPS
- Impact of buffer and surfactant on size and structure of LPS
- Mechanistic drivers of LER

**Bacterial Endotoxin Test: Inhibition and Enhancement**
- Current industry examples interference, both inhibition and enhancement
- Case studies and solutions for overcoming interference

### Speakers

**DR MARKUS DATHE, *F. Hoffmann-La Roche, Switzerland***

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

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

**DR DAYUE CHEN, *Eli Lilly***

**DR TARIK KHAN, *F. Hoffmann-La Roche***

**DR KLAUS BRANDENBURG, *Borstel Research Center***

**JOHN DUBCZAK, *Charles River Laboratories***

**DR JENNIFER FARRINGTON, *Associates of Cape Cod***

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**Speakers**

**PROF DR KLAUS BRANDENBURG, *Borstel Research Center, Germany***
Scientist at Borstel Research Center and Professor (apl.) at University Kiel.

**DR DAYUE CHEN, *Eli Lilly and Company***
Bioproduct Process Development.

**JOHN DUBCZAK, *Charles River Laboratories***
General Manager.

**DR JENNIFER FARRINGTON, *Associates of Cape Cod***
Works in Quality Control and Regulatory departments.

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

**DR TARIK KHAN, *F. Hoffmann-La Roche, Switzerland***
Group leader/scientist in late-stage pharmaceutical and processing development, where market formulation development is a key component of his role.

**PROF. JACK LEVIN, *Univ. of California School of Medicine, San Francisco***
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| CMO Experiences with Low Endotoxin Recovery | - The approach of an aseptic contract manufacturer in case of LER  
- Test strategy and risk assessment  
- Case study  
TABEA HILLMAYR, Vetter Pharma-Fertigung |
| Demasking Strategies for complex samples | - Theoretical Thoughts about Demasking  
- Practical Approaches: Componenets needed for Demasking:  
- Case Study: Demasking of Endotoxins in a Biopharmaceutical  
JOHANNES REICH, University Regensburg |
| European Regulation – the increasing need of animal free testing | - Advantages / disadvantages of animal based routine testing  
- EU-Directive 2010/63  
- Impact on Pyrogen / Endotoxin testing  
- EDQM initiative on validation of in-vitro methods  
DR INGO SPREITZER, PEI – German Federal Institute for Vaccines and Biomedicines |
| Recombinant Factor C: Reliable Endotoxin Testing Alternative | - Evolution of Endotoxin QC testing market and methodology  
- Advantages of testing using Recombinant Factor C  
- Recent improvements in Recombinant Factor C-based testing products  
- Current regulatory position of test using Recombinant Factor C  
DR ELENA GUSTCHINA, Lonza |
| MAT using cryopreserved pooled PBMCs | - MAT as pyrogen test  
- Characteristics and Performance of MAT assay of Sanquin  
- Examples of validation and drug release testing of plasma derived products  
DR ASTRID VISSER, Sanquin |
| The Monocyte Activation Test: Its Value as Relates to Other Pyrogen and Impurity Tests | - Applied appropriately, the MAT is a valuable orthogonal tool to inform risk of pyrogenicity or other clinical manifestations  
- Product Mechanism of Action can confound interpretation of MAT – Broad understanding is needed of what it is monitoring  
- The relationship to pyrogenicity in animals is species dependent, yet meaningful relationships are possible  
- Not all endotoxins are created equal – the MAT may illuminate the LER issue  
- Case Studies applying MAT will be provided  
DR NED MOZIER, Pfizer Biotherapeutics |
| Achieving high reactivity and sensitivity with the Monocyte Activation Test (MAT) | - Factors influencing reproducibility and sensitivity of MAT  
- Comparing results of individual donor versus pooled PBMC  
- Overcoming (international) logistics and transportation issues when using frozen PBMC  
SHABNAM SOLATI, MAT Research |

**Speakers**

DR ELENA GUSTCHINA, Lonza, USA  
Scientist, Enzyme and Protein Chemistry, Assay and Process Development.  
TABEA HILLMAYR, Vetter Pharma-Fertigung, Germany  
Head of QC Langenargen.  
DR NED MOZIER, Pfizer Biotherapeutics, USA  
Senior Director of Analytical Research and 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.  
SHABNAM SOLATI, MAT Experiences  
Biomolecular Researcher with 25 years of experience, and Monocyte Activation Test (MAT).  
DR INGO SPREITZER, Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines, Langen, Germany  
Since October 2004 Deputy Head of Section 1/3, “Microbial Safety and Parasitology”.  
DR ASTRID VISSER, Sanquin Plasma Products, The Netherlands  
She coordinates the development of the MAT assay and cells for a robust, reliable assay.
Agenda

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<th>Rapid Microbiological Methods</th>
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<td>Welcome and Introduction</td>
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<td>TR33 and Ph. Eur. 5.1.6</td>
<td>biopharmaceuticals</td>
<td>Prof Jack Lewis. Unv. of</td>
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<td>Dr Michael Miller, Microbiology Consultants</td>
<td>Dr Manuela Leitner, AGES – Austrian Agency for Health &amp; Food Safety</td>
<td>California School of Medicine</td>
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<td>Detection of pyrogenic contaminants in raw materials</td>
<td>FDA's current Thinking on LER</td>
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<td>Sampling in a Sterile Environment</td>
<td>Dr Neja Fritsch, Conforama France</td>
<td>Patricia Hughes, Ph.D., FDA</td>
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<td>Assessing the Microbiology Laboratory for Data Integrity Issues - an auditor’s perspective</td>
<td>Virus risk minimisation strategies for biopharmaceutical products Dr Ralf Klein, VirSure</td>
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<td>Dr Astrid Visser, Sanguin</td>
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<td>Reduced Testing of Excipients Dr Ingel Mecklenbräucker, Novartis Pharma Stein</td>
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<td>Prof Dr Klaus Brandenburg, Barstel Research Center</td>
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<td>Dr Tarik Khan, F. Hoffmann-La Roche</td>
<td>Shabnam Soletil, M4T Research</td>
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<td>Validation Strategy for Rapid Microbial Detection Celis AMPScreen</td>
<td>Microbiological Aspects of Water and Biofilms Christine Wofk, Labor L+S</td>
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<td>17.30 h</td>
<td>Dr Ron Smith, Janssen Pharmaceuticals</td>
<td>Final Discussion</td>
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<td>18.00 h</td>
<td>Social Event for Congress Delegates, Speakers and Exhibitors (8 November)</td>
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If the event must be cancelled, registrants will be notified as instructors, or speakers without notice or to cancel an event within 1 week prior to the conference 100%. Until 1 week prior to the conference 50%, until 2 weeks prior to the conference 10%, the following processing fees: Cancellation 2. If you have to cancel entirely we must charge 1. We are happy to welcome a substitute colleague at any time. If you cannot attend the conference you have two options: General terms and conditions

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 30%.
   - until 1 week prior to the conference 50%.
   - within 1 week prior to the conference 100%.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid.

### Dates
Tuesday, 8 November 2016, 09.00 – 18.00 h
Wednesday, 9 November 2016, 09.00 – 18.00 h
(Registration Monday, 7 November, 19.00 – 20.30 h and Tuesday, 8 November/Wednesday, 9 November 08.00 – 09.00 h)

### Venue
Swissôtel Düsseldorf / Neuss
Rheinallee 1
D-41640 Neuss
Germany
Tel.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
Email@swissotel-duesseldorf.de

### Fees
€ 690,- (€ 345,- for EU GMP Inspectors) for one day ticket plus VAT
€ 1380,- (€ 690,- for EU GMP Inspectors) 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. VAT is reclaimable.

Your registration also entitles you to participate in all other PharmaLab Congress conferences during the day of your conference or 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 be no 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
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D-69007 Heidelberg
Phone +49 (0) 62 21/84 44-0; Fax +49 (0) 62 21/84 44 34
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**For questions regarding content:**
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### Fees
Part of PharmaLab 2016, Düsseldorf/Neuss, Germany, 8-9 November 2016

I would like to attend the following conference(s):

- Rapid Microbiological Methods (8 November 2016)
- Microbial Safety of Raw Materials and Excipients (9 November 2016)
- Endotoxin and Pyrogen Testing (8/9 November 2016)

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