Low Endotoxin Recovery/Masking
Hands-on Laboratory Training Course

26/27 February 2019, Munich/Bernried, Germany

SPEAKERS:

Dr. Ingo Ciolkowski
Lonza Cologne GmbH

John Dubczak
Charles River Laboratories

Stefan Gärtner
Labor LS

Dr Holger Grallert
Hyglos GmbH

Dr Andreas Karst
Haemochrom Diagnostica

Dr Johannes Reich
Microcoat Biotechnologie GmbH

Kevin Williams
bioMérieux

Veronika Wills
ACC

HIGHLIGHTS:

- Interpretation of interference during Endotoxin detection
- Understanding Low Endotoxin Recovery (LER)
- Setup of hold-time studies
- Techniques for demasking Endotoxin

This education course is recognised for the ECA GMP Certification Programme „Microbiological Laboratory Manager“. Please find details at www.gmp-certification.eu
Objectives

- How to identify Low Endotoxin Recovery (LER)
- How to Set-up hold-time studies
- Analysis of influencing factors (Sample matrices, endotoxin, temperature, detection methods, etc.)
- Understanding the driving forces of LER
- Interpretation of test results
- Dedicated sample treatment for demasking

Background

In the last years the LAL test has become the preferred system to test for endotoxins – for the in-process control as well as in the final inspection – and it is anchored in the pharmacopoeias. However, in the recent past, the problem of low endotoxin recovery employs the pharmaceutical microbiology. Masking – or not? Evidence gaps? And how can I close them? And how to evaluate?

These are the questions the pharmaceutical microbiologists as well as those responsible for the release have to deal with.

And last but not least, how can we handle the test in daily business in a practical manner?

Target Audience

- Laboratory management and staff of pharmaceutical microbiology
- Microbiologists and laboratory assistants from contract laboratories
- Scientific staff from the area Endotoxin testing

Social Event

On the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Moderators

Dr Johannes Reich, Microcoat
Axel H. Schroeder, Concept Heidelberg

Programme

Endotoxin Detection Methods I
- Definition of Endotoxins
- Nature of Endotoxin
- General detection methods

Endotoxin Detection Methods II
- Basic reaction of Limulus-based detection methods
- Sample handling
- Construction and interpretation of standard curve

LER: Reflecting on Biopharmaceutical Operational Reality
- Mechanisms of LER can be influenced by LPS stability
- Varying size and fragility of LPS aggregates can be directly correlated to presence of chelating agents and detergents
- Elucidating conformational changes, in real time, on LPS using HSAFM

Test Interference
- Positive Product Control (PPC)
- Test inhibition
- Test enhancement

Test Interference II (Enhancement)
- Experiences with Interferences
- Test enhancement

Endotoxin Recovery Studies for the Detection of Endotoxin Masking Effects
- Endotoxin Masking
- Planning and implementation of hold-time studies
- Interpretation of hold-time studies

Demasking of Endotoxin
- Mechanistic principles of demasking
- Development of demasking protocols
- Implementation of demasking protocols

Sample Preparation for Demasking
- Practical demasking procedure
- Preparation of reagents for demasking
- Application of demasking protocols
Biologics are Different
- Microbiological Control
- The new science of immunological control

Round Table Discussion
Practical Laboratory Work

Simulation of contamination in various sample matrices
- Preparation of samples affected by
  - Test interference
  - Sample interference

Analysis of interference in affected samples
- Application of different detection systems
  - Limulus Amebocyte Lysate assay
  - Recombinant Factor C assay

Sample treatment for demasking
- Screening for demasking protocol
- Optimization of demasking protocol
- Evaluation of demasking protocol

Interpretation and Comparison of Results
- Differentiation between test and sample interference
- Effects of different detection systems
- Demasking of endotoxin

Closing Remarks (ECA Academy)

Speakers

Dr. Ingo Ciolkowski, Lonza Cologne GmbH
After studying and his degree, Ingo worked as researcher scientist at the University Gießen. From 2007 – 2011 he was employed at QIAGEN. Since 2011 he is Scientific Support Specialist at Lonza and handles all Endotoxin related questions as well as manages the application lab for LAL assay trouble shooting.

John Dubczak, General Manager at Charles River, USA
John was a long-term employee of Baxter Healthcare Corp., where he developed Baxter’s proprietary LAL formulation and manufacturing process. With seven years of LVP manufacturing experience, he brings an in-depth understanding of issues surrounding all aspects of LAL testing in the pharmaceutical industry.

Stefan Gärtner, Labor LS, Germany
After his qualification as biological laboratory technician at LS Stefan worked as technical specialist at LS. 2015 he finished his studies at Provadis School of International Management and Technology wit a BSc in Biopharmaceutical Sciences. Since May, he is head of a speciality department at Labor LS.

Dr Holger Grallert, Hyglos GmbH, Germany
Dr. Holger Grallert is Vice President Research and Development at Hyglos GmbH, Bernried, Germany. His unit is focused on the improvement of existing and development of new analytical methods in the field of Bacterial Endotoxins.

Dr Andreas Karst, Haemochrom Diagnostica, Germany
Andreas Karst studied Chemistry at the University of Münster. His dissertation was at the Institute for Inorganic Chemistry of the University of Münster. He is employed by Haemochrom Diagnostica GmbH since 1997.

Dr Johannes Reich, Microcoat Biotechnologie GmbH, Germany
Johannes holds a degree in Business administration and a PhD from the University Regensburg. In 2016, Johannes joined Microcoat Biotechnology GmbH and has recently been appointed General Manager.

Kevin Williams, bioMérieux, USA
Kevin is a recognized expert in the endotoxin detection field with over 30 years of experience in Pharma (Eli Lilly, Hospira and Lonza). He authored and edited the 2nd and 3rd editions of “Endotoxins” book from Informa Healthcare as well as authoring many journal articles in PDA, BioPharm, Pharmaceutical Technology, and American Pharmaceutical Review.

Veronika Wills, Associates of Cape Cod, Inc., Assistant Manager of Technical Services
Veronika Wills joined the team in 2007. She manages the Technical Services group at Associates of Cape Cod, Inc.
If the bill-to-address deviates from the specifications on the right, please fill out here:

**Reservation Form (Please complete in full)**

**Low Endotoxin Recovery/Masking**  
26/27 February 2019, Munich/Bernried, Germany

- **Mr.**  
- **Ms.**

**Title, first name, surname**

**Company**  
**Department**

**Important**: Please indicate your company’s VAT ID Number  
**P.O. No** if applicable

**Street/P.O. Box**  
**City**  
**Zip Code**  
**Country**

**Important**: This is a binding registration and above fees are due in case of cancellation or non-attendance. 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!! (As of January 2012)

**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 fee is reclaimable 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!! (As of January 2012)

**Terms of payment**  
**Payable without deductions within 10 days after receipt of invoice.**

**FEES (per delegate plus VAT)**

- **EU GMP Inspectorates**: € 995
- **APIC Members**: € 1,890
- **ECA Members**: € 1,790
- **Non-ECA Members**: € 1,990
- **ECA Members**: € 1,790
- **Non-ECA Members**: € 1,990

**Venue of the Laboratory Course**  
**Microcoat Biotechnologie GmbH**
Am Neuland 3, 82347 Bernried am Starnberger See

**Shuttle Service from to Munich Airport**
- On 25 February at appr. 19.00 from Munich Airport to Bernried Marina Hotel.
- On 27 February at appr. 12.30 from Munich Airport to Microcoat to Bernried Marina Hotel.

**Date**
- **Tuesday, 26 February 2019**: 09.30 – 17.30 h
- **Wednesday, 27 February 2019**: 09.00 – 09.30 h

**Conference Language**
- The official conference language will be English.

**Conference and Training**
- On 28 February in Bernried at Microcoat, starting at 10.00 h, participations are only possible if you have registered beforehand.

**Overnight Stay**
- **Hotel Marina**
  - Am Neuland 3, 82347 Bernried am Starnberger See
  - info@hotelmarina.de
  - +49(0)8158 -9320
  - www.hotelmarina.de

**Conception Concept Heidelberg**
- +49 (0) 62 21/84 44-10, schoeder@concept-heidelberg.de
- +49 (0) 62 21/84 44 46, weidemaier@concept-heidelberg.de.

**For questions regarding reservation, hotel, organisation etc. please contact:**
- Ms Marion Weidemaier (Organisation Manager) at +49 (0) 62 21/84 44 46, weidemaier@concept-heidelberg.de.
- Mr Axel H Schroeder (Operations Manager) at +49 (0) 62 21 / 84 44 10, schroeder@concept-heidelberg.de.

**Accommodation**
- **Hotel Marina**: Am Neuland 3, 82347 Bernried am Starnberger See
- info@hotelmarina.de, www.hotelmarina.de

**Shuttle Service**
- Transfer-service is included from Mariona Hotel to Microcoat in the morning and back in the evening will be organised.

**General Information**
- German law shall apply. Court of jurisdiction is Heidelberg.

**Privacy Policy**
- By registering for this event, I accept 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).

**Important**: I note that I can ask for the modification, correction or deletion of my personal data at any time via the contact form on this website.