

Low Endotoxin Recovery/Masking

Hands-on Laboratory Training Course

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



Practical Laboratory Training
in small groups –
max 15 participants.

26/27 February 2019, Munich/Bernried, Germany

HIGHLIGHTS:

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



Low Endotoxin Recovery/Masking

26/27 February 2019, Munich/Bernried, Germany

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



Image: Charles River

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



Image: Labor LS

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 research 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 Pro-
vadis School of International Management and Technology with 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.

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.gmp-compliance.org



+ 49 6221 84 44 34

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

Phone/Fax

E-Mail (please fill in)

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice. Court of jurisdiction is Heidelberg. German law shall apply.

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Date

Tuesday, 26 February 2019, 09.30 - 17.30 h
(Registration and coffee 09.00 - 09.30 h)
Wednesday 27 February 2019, 08.30 - 17.00 h

Overnight Stay

Hotel Marina
Am Yachthafen 1-15
82347 Bernried am Starnberger See, Germany
Phone +49(0)8158 -9320
Email info@hotelmarina.de

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the event. Reservation should be made directly with the hotel no. Early reservation is recommended.

Venue of the Laboratory Course

Microcoat Biotechnologie GmbH
Am Neuland 3, 82347 Bernried am Starnberger See

Transfer service from Marina Hotel to Microcoat in the morning and back in the evening will be organised

Shuttle Service from/to Munich Airport

On 25 February at appr. 19.00 from **Munich Airport** to **Bernried Marina** Hotel.
On 27 February at approx. 17.15 h from **Microcoat** to **Munich Airport**.

Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Participants of the Monocyte Activation Test Laboratory Training on 28 February/01 March in Bernried get a € 200 discount.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Conference Language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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For questions regarding reservation, hotel, organisation etc. please contact:
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