

## Speakers



John Dubczak  
Charles River  
Laboratories



Stefan Gärtner  
Labor LS



Dr Holger Grallert  
Hyglos



Dr Andreas Karst  
Haemochrom  
Diagnostica



Dr Johannes Reich  
Microcoat  
Biotechnologie



Kevin Williams  
bioMérieux



Veronika Wills  
ACC



Dr Thomas Winkler  
Lonza Cologne

# Low Endotoxin Recovery/Masking

Hands-on Laboratory Training Course

11/12 February 2020 | Munich/Bernried, Germany



## Highlights

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

Practical Laboratory Training  
in small groups – max 15 participants.

## Objective

- 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 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 Endotoxin testing area

## Moderators

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

## Social Event



In the evening of 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.

## Programme

### Endotoxin Detection Methods I

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- Definition of Endotoxins
- Nature of Endotoxin
- General detection methods

### Endotoxin Detection Methods II

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- Basic reaction of Limulus-based detection methods
- Sample handling
- Construction and interpretation of standard curve

### LER: Reflecting on Biopharmaceutical Operational Reality

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- 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 I (Inhibition)

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

### Test Interference II (Enhancement)

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- Experiences with Interferences
- Test enhancement

### Technical Report - Guidance for LER Hold time studies

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- Endotoxin Masking
- Planning and implementation of hold-time studies
- Interpretation of hold-time studies

### Demasking of Endotoxin

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

### Sample Preparation for Demasking

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- Practical demasking procedure
- Preparation of reagents for demasking
- Application of demasking protocols

### Biologics are Different

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- Microbiological Control
- The new science of immunological control

## 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

## Speakers



**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 Provdavis 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, USA

Veronika Wills joined the team in 2007. She manages the Technical Services group at Associates of Cape Cod, Inc.



**Dr Thomas Winkler,**  
Lonza Cologne GmbH, Germany

Dr Thomas Winkler studied at the university of Mainz and Hamburg University of Technology where he finished his PhD in the field Physiology and Biomaterials. After his degree he worked as Sales Manager Biopharma for Miltenyi Biotech GmbH and Global Product Manager for Automated Solutions for QIAGEN. Since 2017 he has been working at Lonza Cologne as Product and Sales Specialist for Endotoxin Testing.

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

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### Reservation Form (Please complete in full)

- Low Endotoxin Recovery/Masking, 11/12 February 2020, Munich/Bernried, Germany
- Monocyte Activation Test (MAT), 13/14 February 2020, Munich/Bernried, Germany

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

ZIP Code

Country

Phone / Fax

E-Mail (Please fill in)

CONCEPT HEIDELBERG

P.O. Box 101764

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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 %
  - Cancellation until 1 week prior to the conference 50 %
  - Cancellation 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 can-

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!) (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

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](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.

## 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 Course" on 13/14 February 2020 in Bernried get a € 200 discount.

## 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 course. Reservation should be made directly with the hotel. Early reservation is recommended.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://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.

CONCEPT HEIDELBERG

P.O.Box 10 17 64 | 69007 Heidelberg, Germany

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[info@concept-heidelberg.de](mailto:info@concept-heidelberg.de) | [www.concept-heidelberg.de](http://www.concept-heidelberg.de)

For questions regarding content please contact:

Mr Axel H. Schroeder (Operations Director) at

+49(0)62 21/84 44 10, or at

[schroeder@concept-heidelberg.de](mailto:schroeder@concept-heidelberg.de).

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

Ms Isabell Neureuther (Organisation Manager) at

+49(0)62 21/84 44 49, or at

[neureuther@concept-heidelberg.de](mailto:neureuther@concept-heidelberg.de).

## Date

Tuesday, 11 February 2020, 09.30 – 17.30 h

(Registration and coffee 09.00 – 09.30 h)

Wednesday, 12 February 2020, 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](mailto:info@hotelmarina.de)

## Venue of the Laboratory Course

Microcoat Biotechnologie GmbH

Am Neuland 3, 82347 Bernried am Starnberger See, Germany

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 10 February at appr. 19.00 h from Munich Airport to Hotel

Marina. On 12 February at appr. 17.15 h from Microcoat to

Munich Airport.