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.
Programme

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

- 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 I (Inhibition)

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

Test Interference II (Enhancement)

- Experiences with Interferences
- Test enhancement

Technical Report - Guidance for LER Hold time studies

- 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

Misconceptions in LAL/rFC testing

- Masking
- rFC/LAL specificity
- LAL and beta-glucans
- Compendial update of rFC
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 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.

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.
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)

General terms and conditions

Or you register online at www.gmp-compliance.org.

Fees (per delegate, plus VAT)

EU GMP Inspectorates € 995
Non-ECA Members € 1890
ECA Members € 1790

Participants of the "Monocyte Activation Test Laboratory Training Course" on 13/14 February 2020 in Bernried get a € 200 discount.

The official conference language will be English.

Conference and Contact

The conference language will be English.

Or you register online at www.gmp-compliance.org.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form upon registration. 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.

Venue of the Laboratory Course

Date

Registration

Via the attached reservation form, by e-mail or by fax message.

Accommodation

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