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

SPEAKERS:

Stefan Gärtner
L+S AG

Dr Holger Grallert
Hyglos GmbH

Dr Saskia Ihle
Lonza

Thomas Potrawfke
Haemochrom Diagnostica

Johannes Reich
University of Regensburg

Marion Usedom
Charles River Laboratories

Dr Friedrich von Wintzingerode
Roche Diagnostics GmbH

HIGHLIGHTS:

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

24-25 November 2015, Munich/Bernried, Germany

Hands-on Laboratory Training Course

Low Endotoxin Recovery/Masking

Practical Laboratory Training in small groups – max 15 participants.
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

Programme

Endotoxin Detection Methods I

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

Thomas Potrawfke, Haemochrom Diagnostica

Endotoxin Detection Methods II

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

Dr Saskia Ihle, Lonza

Utilizing high speed atomic force microscopy (HSAFM) to observe the conformational changes and stability of LPS, in the presence of detergents, and its impact on biological activity and LER. 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

Marion Usedom, CRL

Test Interference

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

Stefan Gärtner, L+S

Sample Interference (LER)

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

Dr Friedrich von Wintzingerode, Roche Diagnostics GmbH

Demasking of Endotoxin

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

Johannes Reich, University Regensburg

Social Event

On 24 November, 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.
Sample Preparation for Demasking
- Practical demasking procedure
- Preparation of reagents for demasking
- Application of demasking protocols

Dr Holger Grallert, Hyglos

Round Table Discussion

Practical Laboratory Work
(Microcoat GmbH)

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

Endotoxin Service Team, Microcoat GmbH

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

Endotoxin Service Team, Microcoat GmbH

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

Endotoxin Service Team, Microcoat GmbH

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

Endotoxin Service Team, Microcoat GmbH

Closing Remarks (ECA Academy)

Speakers

Stefan Gärtner, Labor L+S AG, Bad Bocklet, Germany
After his qualification as biological laboratory technician at L+S AG Stefan worked as technical specialist at L+S. 2015 he finished his studies at Provdais School of International Management and Technology wit a BSc in Biopharmaceutical Sciences. Since May, he is head of a specialty department at L+S AG.

Dr Holger Grallert, Hyglos GmbH, Bernried, 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. He brings twenty years of microbiology and biochemistry expertise in the development and introduction of diagnostic and preparative tools to academic and industrial marketplaces. Beforehand, he studied Biology at the University of Regensburg and received his PhD from the Technical University of Munich.

Dr Saskia Ihle, Scientific Support Specialist at Lonza Cologne GmbH
Saskia studied Biotechnology in Mannheim and holds a PhD in Biochemical Engineering. She is employed at Lonza Cologne GmbH as Scientific Support Specialist with several years of experience in endotoxin testing. Today, she is also responsible for Endotoxin Detection Trainings.

Thomas Potrawfke, Haemochrom Diagnostica, Essen, Germany
Thomas Potrawfke has a degree in Biology from the Technical University Braunschweig where he focused on microbiology and biochemistry. He started at Lonza (formerly BioWhittaker (Cambrex)) in 2000, where he held various positions, in the end as Key Account Manager. Most recently he joined Haemochrom Diagnostica as a Product Manager, a company experienced in haemostasis diagnostics and endotoxin analytics for more than 20 years.

Johannes Reich, University Regensburg, Germany
Johannes Reich studied business administration and chemistry in Regensburg. Currently, he is working on his doctoral thesis on “function-structure relationship of Lipopolysaccharide with recombinant factor C test systems” at the Institute for physical and theoretical chemistry. He deals with the problems of modern endotoxin detection methods and with the problem of low endotoxin recovery. In the meantime he worked as product manager at Profos AG in Regensburg.

Marion Usedom, Regional Specialist Manager, Endotoxin & Microbial Detection, Charles River Laboratories
Marion is a biological technician by training. From 1993-2003 she worked in microbiological QC at Haupt Pharma. Since 2003 she is working for Charles River Laboratories. Currently she is managing a sales and application specialist team of seven team members for the business unit Endotoxin and Microbial Detection.

Dr Friedrich von Wintzingerode, Roche Diagnostics GmbH, Penzberg, Germany
Friedrich studied biology with focus on Microbiology at Technical University Braunschweig. Diploma at German Strain Culture Collection (DSMZ), Braunschweig. Degree at Institute of Microbiology and Hygiene, Charité, Berlin. Since 2001 employed at Roche Diagnostics as group leader Environmental monitoring and cleaning analytics and since 2005 group leader microbio- logical IPC and analytics for release. Friedrich is Head of a global working group for microbial identification within Roche and Senior Manager QC Microbiology. Lead of Endotoxin Expert Group Roche/Genentech.
Low Endotoxin Recovery/Masking
24-25 November 2015, Munich/Bernried, Germany

Reservation Form (Please complete in full)

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Street/P.O. Box

City  Zip Code Country

Phone/Fax  E-Mail (please fill in)

Date

Tuesday, 24 November 2015, 12.45 – 18.00 h

(Registration and come-together 11.00 - 12.00 h, Lunch 12.00 - 12.45 h)

Wednesday, 25 November 2015, 08.30 – 17.00 h

Overnight Stay

Hotel Marina

Am Yachthafen 1-15

82347 Bernried am Starnberger See,

Germany

Phone +49(0)8158 -9320

Fax  +49(0)8158-7117

info@hotelmarina.de

Venue of the Laboratory Course

Microcoat Biotechnologie GmbH

Am Neuland 3, 82347 Bernried am Starnberger See

Transfer service from Marina Hotel to Microcoat will be organised.

Shuttle Service from/to Munich Airport

On 23 November at appr. 19.00 from Munich Airport to Bernried Marina Hotel.

On 25 November at approx. 17.15 h from Microcoat to Munich Airport.

Fees (per delegate plus VAT)

ECA Members € 1,490

APIC Members € 1,590

Non-ECA Members € 1,690

EU GMP Inspectorates € 845

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

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

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

www.gmp-compliance.org

www.microma.com

Price includes hotel, return airport transfer, meals and refreshments.

Important: This is an empty registration form which you may use to book your accommodation. Please make your hotel reservation directly with the hotel. Early reservation is recommended.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee then be calculated according to the point of time at which you receive your message. If no information is received, we will take the fees by full registration fee. If you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference/registration will not be confirmed if (As of January 2012)

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

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

For questions regarding organisation, contact

Ms Marion Weidemaier (Organisation Manager at

+49-62 21 / 84 44 46, weidemaier@concept-heidelberg.de

For questions regarding content, contact

Mr Axel H Schroeder (Operations Manager at

+49-62 21 / 84 44 10, schroeder@concept-heidelberg.de

For questions regarding reservation, hotel organisation etc.

info@concept-heidelberg.de, www.concept-heidelberg.de

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 the order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information on 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/data_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 our website.