

Academy Your GMP/GDP Information Source

Low Endotoxin Recovery/Masking

Hands-on Laboratory Training Course

SPEAKERS:

Dr Ingo Ciolkowski Lonza AG

John Dubczak Charles River Laboratories

Stefan Gärtner L+SAG

Dr Holger Grallert Hyglos GmbH

Thomas Potrawfke Haemochrom Diagnostica

Johannes Reich University of Regensburg

Dr Friedrich von Wintzingerode Roche Diagnostics GmbH Practical Laboratory Training in small groups – max 15 participants.

13-14 December 2016, 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

13-14 December 2016, 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 Rive

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 10 February, 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

Thomas Potrawfke, Haemochrom Diagnostica

Endotoxin Detection Methods II

- Basic reaction of Limulus-based detection methods
- Sample handling
- Construction and interpretation of standard curve
- Dr Ingo Ciolkowski, Lonza

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

John Dubczak, CRL

Test Interference

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

Stefan Gärtner, L+S



Image: Labor L+S

Endotoxin Recovery Studies for the Detection of Endotoxin Masking Effects

- 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

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

Dr Ingo Ciolkowski, Lonza AG

Dr Ciolkowski studied at the University of Kaiserslautern, and Cologne where he finished his PhD at the Max-Planck-Institute for Plant Breeding Research. After his degree, he 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

Prior to joining Charles River, John was a long-term employee of Baxter Healthcare Corp., where he developed Baxter's proprietary LAL formulation and manufacturing process. As a member of the R&D team, he also developed methods for product testing and explored the clinical applications of LAL. With seven years of LVP manufacturing experience, he brings an indepth understanding of issues surrounding all aspects of LAL testing in the pharmaceutical industry.

Stefan Gärtner, Labor L+SAG, 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 Provadis School of International Management and Technology wit a BSc in Biopharmaceutical Sciences. Since May, he is head of a speciality 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. 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.

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 microbiological 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.

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