Low Endotoxin Recovery/Masking
Hands-on Laboratory Training Course

05/06 March 2024 | Munich/Bernried, Germany

Highlights

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

Speakers

Aoife Barron
Lonza Biologics

Jacqueline Dünisch
Labor L+S

Dr Christian Faderl
bioMérieux Deutschland

David Guy
ACC

Dr Bernhard Illes
Microcoat

Dr Holger Kavermann
Roche

Dr Michael Kracklauer
Microcoat

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 (Focus on LAL)

- Definition of Endotoxins
- Basic reaction of Limulus-based detection methods
- General LAL-based detection methods
- Construction and interpretation of standard curve

Endotoxin Detection Methods II (Focus on rFC)

- General rFC-based detection methods
- Sample handling
- Interpretation of results

Test Interference I (Inhibition)

- Positive Product Control (PPC)
- Test inhibition

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

Sample Interference/Hold Time Case Studies

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

Mechanistic Principles of Endotoxin Masking and Demasking

- Mechanistic principles of masking
- Mechanistic principles of demasking

Mitigation of LER - General Approach

- General mitigation approaches
- Development of dedicated mitigation protocols to overcome LER
- Case Studies
Sample Preparation to Reverse the LER Effect

- The ENDO-RS technology for endotoxin demasking
- Demasking protocol development - a case study
- Application of demasking protocols

Validation of Demasking Method using rFC-based Assay

- Demasking as sample treatment to overcome LER effect
- Validation of a rFC based method
- Combination of demasking and rFC as release test for DP

Practical Laboratory Work at Microcoat

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

Aoife Barron, Lonza Biologics
Aoife Barron is a Business Development Manager in Bioscience Sales at Lonza Biologics AG since July 2022. Aoife has extensive experience as a bio-processing and QC Micro trainer at NIBRT, Dublin, and has worked as a QC Micro Specialist for companies such as Wyeth, Pfizer and Amgen, where she developed her skills as an Endotoxin Testing SME. Aoife graduated from NUI Maynooth, Ireland in 2007 with a Biological Sciences degree.

Jacqueline Dünisch, Labor LS
After completing her Master’s degree in Molecular Sciences at the University of Erlangen-Nuremberg, Jacqueline joined Labor LS in 2016 and has since been in charge of endotoxin testing.

Dr Christian Faderl, bioMérieux
Christian Faderl joined bioMérieux in 2017. As Project Coordinator and Manager, he is in charge of endotoxin service projects like feasibility studies and demasking projects.

David Guy, Associates of Cape Cod, Inc.,
David Guy is Technical Manager for Associates of Cape Cod. 2023 will see his 30th year in the field of Bacterial Endotoxin Testing and his 10th year at Associates of Cape Cod where he helped develop the endotoxin testing application, Pyros® eXpress. His experience covers both Sales and Technical Support for products and methodologies from natural lysate to recombinant reagents and manual techniques to automation of the BET test.

Dr Bernhard Illes, Microcoat
Bernhard Illes studied chemistry at LMU Munich and did his PhD on nanoparticles and protein activation. He is currently a project manager at Microcoat with a focus on development projects for the mitigation of endotoxin masking in pharmaceutical samples.

Holger Kavermann, Roche Diagnostics
Holger Kavermann studied microbiology at the University of Göttingen and obtained his PhD in medical microbiology at the University of Munich. In 2003, he joined Roche Diagnostics GmbH as Manager QC responsible for the microbiological and cell biological analytics of QC and In-Process-Control-samples in the production of biotechnological derived active pharmaceutical ingredients. In 2013, he became head of the QC Department for Environmental Monitoring and Cleaning Validation. Since 2017, he has been the department head for Microbiology, EM and Cleaning Analytics.

Dr Michael Kracklauer, Microcoat
Dr. Michael Kracklauer studied Biotechnologie. He received his PhD from the RWTH Aachen University. The research topic was the field of protein misfolding and amyloid diseases with focus on Alzheimer’s Disease. He is since 2018 at Microcoat in the department “Endotoxin Services”, with responsibilities for the topics LER, rFC, method development and validation.

Low Endotoxin Recovery/Masking | 05/06 March 2024, Munich/Bernried, Germany
If the bill-to-address deviates from the specifications on the right, please fill out here:

| Low Endotoxin Recovery/Masking, 05/06 March 2024, Munich/Bernried, Germany |
| Monocyte Activation Test (MAT), 07/08 March 2024, Munich/Bernried, Germany |

Title, first name, surname

Department

Company

Important: Please indicate your company’s VAT ID Number

Purchase Order Number, if applicable

City

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For questions regarding organisation etc. please contact:

M. Isabell Helm (Organisation Manager) at
info@concept-heidelberg.de  |  www.concept-heidelberg.de
Phone +49(0)62 21/84 44-0  |  Fax +49(0)62 21/84 44 34
P. O. Box 10 176 4  |  69007 Heidelberg, Germany

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