ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

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

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

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 bioprocessing 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 in Erlangen-Nuremberg, Jacqueline joined Labor LS in 2016 and was responsible for endotoxin testing for over 5 years. She is currently responsible for the development of suitability tests for sterile testing of pharmaceutical products.

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.

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CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Low Endotoxin Recovery/Masking
05/06 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 | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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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 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). 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.

Date

Tuesday, 05 March 2024, 09.30 – 17.15 h
(Registration and coffee 09.00 – 09.30 h)
Wednesday, 06 March 2024, 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@marina-bernried.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 06 March at appr. 19.00 h from Munich Airport to Hotel Marina.
On 08 March at appr. 17.15 h from Microcoat to Munich Airport.

Fees (per delegate, plus VAT)

ECA Members € 1,990
APIC Members € 2,090
Non-ECA Members € 2,190
EU GMP Inspectorates € 1,095
The fee is payable in advance after receipt of invoice and includes 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 Hotel Marina. 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.

Presentations / Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at 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.
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