ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Jacqueline Dünisch
Labor LS

Maria Gajewi
Microcoat

Dr Marcus Gutmann
Julius Maximilians University Würzburg

Dr Ruth Röder
Microcoat

Dr Ingo Spreitzer
Paul-Ehrlich-Institut

Dr Sandra Stoppelkamp
University Tübingen and South Westphalia University of Applied Sciences

Delphine Trélat
Sanofi Pasteur

Monocyte Activation Test (MAT)

Hands-on Laboratory Training Course

07/08 March 2024 | Munich/Bernried, Germany

Highlights

- Explanation of the MAT principle
- Understanding pharmacopoeial requirements
- Discussion of case studies
- Hands-on experience in performing the MAT in the laboratory

Practical Laboratory Training
in small groups – max 15 participants.

Objective

This unique event is organised to gain practical experience in performing the Monocyte Activation Test. Further, it brings together industry and regulatory representatives in order to discuss the practical experiences in using MAT, the advantages, the pitfalls, the available systems as well as the regulatory experiences. The purpose is to provide the participants with guidance and support and hands on laboratory training for the implementation and use of the MAT.

Background

During recent years manifold advances have taken place to replace both, Rabbit Pyrogen Test (RPT) and in some cases the Limulus Amebocyte Lysate Test (LAL).

Some of the reasons are:

- Animal experiments have to be reduced. Especially with the current EU Regulations.
- Reduction of variance by validatable in-vitro test methods
- Get an alternative test, where the classic LAL shows some gaps, e.g. contamination of biologicals by non-endotoxin pyrogens not detectable in LAL test is not unlikely.

True In-vitro Pyrogen Tests (IVPT) have been developed in several European countries (United Kingdom, The Netherlands, Switzerland, Germany) in national and international research projects. The tests imitate the central step of human fever reaction, i.e. the activation of human monocytes by endotoxin as well as non-endotoxin pyrogens. One result of all these activities is the Monocyte Activation Test (MAT).

Following, with continuous support by the German Pharmacopoeia, the EDQM MAT Expert group was re-established and finally the MAT Monograph 2.6.30. was implemented into the European Pharmacopoeia in 2010. Meanwhile, the EDQM performed a MAT-survey to improve the MAT monograph and the BET-Guideline 5.1.10. and the Rabbit Pyrogen Test (RPT) monograph, 2.6.8. have been revised to clarify the priorisation of the MAT compared to the RPT (especially in regards to the EU directive 2010/63). However, there are still open questions how MAT can be applied in a routine lab for release testing. The meeting will give guidance for proper use of MAT and strengths and weaknesses will be discussed.

Target Audience

This course is addressed to all persons of

- pharmaceutical manufacturers
- biopharmaceutical companies
- medical device manufacturers
- contract laboratories
- tissue establishments
- authorities

who are involved in Endotoxin and Pyrogen Testing in development, IPC or release.

Programme

Pyrogens – Fever Inducing Agents and the Principle of the Monocyte Activation Test

- What are pyrogens?
- Diversity of pyrogens
- Activation of the human immune system through TLRs stimulation
- Detection of cytokines using the MAT

MAT - a Compendial Test Method

- Explanation of European Pharmacopoeia 2.6.30
- International status of MAT

Hands-on Training in the Laboratory

- Experimental set-up and preparation of samples (e.g., stimulation of cells)
- Loading of cells on assay plate

Pyrogen Testing - Fever in an Animal‘s Body

- History of the Rabbit Pyrogen Test
- Pharmacopoeial requirements
- Regulatory requirements and animal welfare (EU-Directive 2010/63/EU)
- Field of application
- Future of pyrogene detection

Background and Details on Available Monocyte Activation Tests

- Vendors of MAT
- Composition of the different MATs
- Specifity/Sensitivity

Recap of Day 1

Hands-on Training in the Laboratory

- Measurement of Samples

Development of the MAT on Vaccines Containing Inherently Pyrogenic Components

- Intro to Vaccines and Pyrogens – Choice of method
- MAT development for vaccines containing inherent pyrogen components
- Case Study 1 : Characterization of the absence of NEP
- Case Study 2 : Consistensy of production in the case of product containing intrinsic pyrogen

Challenges in Applying the Monocyte Activation Test for Routine Testing in the QC Environment

- Current regulatory perspectives
- Selection of Monocytes
- Read-out of Cytokines
- Methods

Generic Method and Specific Product Validation of the Monocyte Activation Test

- Development of MAT method
- Generic method validation
- Product-specific validation
- Release testing

Hands-on Laboratory Results

- Presentation of the laboratory results
- Discussion of the results

Moderators

Axel H. Schroeder, Concept Heidelberg
Dr Johannes Reich, Microcoat

Speakers

Jacqueline Dünisch
Labor LS, SME Endotoxin
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.

Maria Gajewi
Microcoat, Project Manager Endotoxin
Maria studied at the Technical University of Leipzig. After working around 4 years as scientist at University of Regensburg and Dresden she joined Microcoat Biotechnology in 2019.

Dr Marcus Gutmann
Julius Maximilians University Würzburg, Academic Counsel
Marcus studied at the Universities of Heidelberg and Würzburg. After his PhD, he worked at the Central Institute of the Bundeswehr Medical services. Following he joined Microcoat Biotechnology as a project manager Endotoxin Services. 2020 he came back to the Julius Maximilians University of Würzburg and is currently an Academic Counsel there. He is currently supplementing his knowledge with a master's degree in health business administration (MHBA).

Dr Ruth Röder
Microcoat, Director Endotoxin Services
Ruth studied Biochemistry in Munich. She worked as a researcher at the LMU in Munich alongside her doctorate. In 2016, she joined Microcoat as a research assistant. Afterwards, she became a rest project manager and group leader at Endotoxin Services. She is currently the director of Endotoxin Services.

Dr Ingo Spreitzer
Paul-Ehrlich-Institut, Deputy Head of Section 1/3, "Microbial Safety
Dr. Ingo Spreitzer studied Biology at the Universities of Mainz and Constance, Germany. Since 2001, he has been working as a scientist at the Paul-Ehrlich-Institute. In October 2004, he was appointed Deputy head of Section 1/3, "Microbial Safety". Duties: Pyrogen testing (rabbit until 2014, now MAT); and Endotoxin Testing (BET and rFC) in different setups. Since 2013, he is Chair of the BET-Working Party of the EDQM.

Dr Sandra Stoppelkamp
University Tübingen and South Westphalia University of Applied Sciences
Dr Sandra Stoppelkamp (PhD) is currently working in the field of haemocompatibility and pyrogen testing of medical devices at the University Hospital Tübingen and at the University of Applied Sciences Iserlohn. She has especially gained experience in using the MAT with diverse variants in clinical settings and on medical devices.

Delphine Trélat
Sanofi Pasteur, Scientist, Analytical Sciences - Immunology
Ms Trélat graduated from an engineer school in biotechnology from the university of Strasbourg in France. She joined Sanofi in 2017 in the biochemistry platform and works now as a scientist in the immunology platform where she is in charge of pyrogen testing on vaccines by Monocyte Activation Test.

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.

If the bill-to-address deviates from the specifications on the right, please fill out here:

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CONCEPT HEIDELBERG
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Monocyte Activation Test (MAT), 07/08 March 2024, Munich/Bernried, Germany
☐ 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 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
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
Thursday, 07 March 2024, 09.00 – 17.15 h
(Registration and coffee 08.30 -09.00 h)
Friday 08 March 2024 08.45 – 16.15 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.

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 laboratory materials, 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.

Participants of the "Low Endotoxin Recovery Laboratory Training Course" on 05/06 March 2024 in Bernried get a € 200 discount.

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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