

Monocyte Activation Test (MAT)

Hands-on Laboratory Training Course

SPEAKERS:

Esther Frey

Novartis Pharma AG



Dr Anja Fritsch

Confarma



Stefan Gärtner

Labor LS



Koen Marijt

MAT Research



Dr Ilka Molitor

Novartis Pharma AG



Dr Ruth Röder

Microcoat



Dr Ingo Spreitzer

Paul-Ehrlich-Institut



Dr Sandra Stoppelkamp

*University Tübingen
and South Westphalia
University of Applied Sciences*



Book in combination with ECA's Low Endotoxin Recovery Laboratory Training and get a € 200 discount.

28 February - 01 March 2019, 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



Monocyte Activation Test (MAT) – Hands-on Laboratory Training

28 February - 01 March 2019, Bernried, Germany

Objectives

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 Pharmacopeia, the EDQM MAT Expert group was re-established and finally the MAT Monograph 2.6.30. was implemented into the European Pharmacopeia 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 prioritisation of the MAT compared to the RPT (especially in regards to the EU-directive 2010/63). However, there 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.

Moderators

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

Programme

Pyrogens – Fever inducing agents and the principal 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

Sandra Stoppelkamp, University Tübingen and University of Applied Sciences Iserlohn

MAT a compendial test method

- Explanation of European Pharmacopoeia 2.6.30
- International status of MAT

Ingo Spreitzer, Paul-Ehrlich-Institute

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

Stefan Gärtner, Labor LS

Pyrogen testing from a Pharma QC perspective

- The Rabbit Pyrogen Test – Pros and Cons for the pharmaceutical industry
- The Monocyte Activation Test – challenges and opportunities

Ilka Molitor and Esther Frey, Novartis

Case study – Cryo blood and Cell-based MAT

- Performance of cryo blood and cell-based MAT
- Pros and Cons of particular systems

Anja Fritsch, Merck/Confarma

Preparation of Samples (e.g., stimulation of cells)

Hands-on training in the Lab

Multiple read-out of cytokines

- Available multiple read-out platforms
- Case study: Comparison of platforms

Ruth Röder, Microcoat Biotechnologie

Recap of day 1

Plenum

Measurement of Samples

Hands-on training in the Lab

Case study – PBMC based MAT

- Performance of PBMC-based MAT Pros and Cons of particular system

Koen Marijt, MAT Research

MAT on medical devices – suitable alternative test method for pyrogen- and material-induced activation?

- How the new ISO 10993-11 guideline affects the testing
- Diversity of the test results with MAT variants
- Possible interpretation of the MAT variant outcomes

Sandra Stoppelkamp, University Hospital, Tübingen and University of Applied Sciences Iserlohn

MAT and its challenges

- Variability of test systems
- Interpretation of test results

Ruth Röder, Microcoat Biotechnologie

Presentation of results

Plenum

Discussion of results

Ruth Röder, Microcoat Biotechnologie

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.

Speakers

Esther Frey, Novartis Pharma AG, Labcoordinator



Dr Anja Fritsch, Confarma

Dr Anja Fritsch joined Confarma, Hombourg (F) in 2011 as Chief Scientific Officer. Having more than 15 years of experience in development of cell based disease models and assays, she is responsible for cell based bioassays (development and routine) since 2011.



Stefan Gärtner, Labor LS

After his qualification as biological laboratory technician at Labor LS. Stefan Gärtner worked as technical specialist in the field of different pyrogene detection methods. In 2015 he finished his studies at Provadis School of International Management and Technology with a BSc in Biopharmaceutical Sciences. Since then he is head of department for Bacterial Endotoxins, Pyrogens and Sterility Testing.



Koen Marijt, MAT Research

During the last 10 years, Koen gained experience in the field of cellular biology at Harvard Medical School, Boston USA, and immunology at the LUMC, Leiden the Netherlands. Now he joined MAT Research responsible for improving the monocyte activation test to replace the current compendial animal test systems.



Dr Ilka Molitor, Novartis Pharma AG

After Ilka received her PhD in biology at the University of Bonn she worked for several years as a project leader and lecturer in academics and later held different positions in the pharmaceutical industry. In 2015 Ilka joined Novartis as a QC Expert and is since then together with her team responsible for pyrogen testing of drug products for QC release.



Dr Ruth Röder, Microcoat

Ruth studied Biochemistry at the LMU in Munich. After she gets her PhD, she joined Microcoat in 2016 and is currently Project Manager at the Endotoxin Services department.



Dr Ingo Spreitzer, Paul-Ehrlich-Institut

Ingo Spreitzer studied Biology at the University of Mainz, Germany, and was awarded a doctorate in 2000. Since 2001 he has been working as a scientist at the Paul-Ehrlich-Institut. In October 2004 he was appointed Deputy head of Section 1/3, "Microbial Safety and Parasitology". Duties: Pyrogen testing (rabbit and alternatives); LAL-Testing.



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 divers variants in clinical settings and on medical devices.

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Reservation Form (Please complete in full)

Monocyte Activation Test (MAT) - Hands-on Laboratory Training

28 February - 01 March 2019, Bernried, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

P.O. No if applicable

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GERMANY

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Date

Thursday, 28 February 2019, 09.00 – 17.30 h,
(Registration and coffee 08.30 - 09.00 h)
Friday, 01 March 2019, 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@hotelmarina.de

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the event. Reservation should be made directly with the hotel no. Early reservation is recommended.

Venue of the Laboratory Course

Microcoat Biotechnologie GmbH
Am Neuland 3, 82347 Bernried am Starnberger See

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 27 February at appr. 19.00 h from **Munich Airport** to **Bernried Marina** Hotel.
On 01 March at approx. 16.30 h from **Microcoat** to **Munich Airport**.

Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
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.

Participants of the Low Endotoxin Recovery Laboratory Training on 26/27 February in Bernried get a € 200 discount.

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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