

Speakers



Esther Frey
Novartis Pharma



Dr Anja Fritsch
Confarma



Stefan Gärtner
Labor LS



Koen Marijt
MAT Research



Dr Ilka Molitor
Novartis Pharma



Ruth Röder
Microcoat



Shabnam Solati
CTL-MAT



Dr Ingo Spreitzer
Paul-Ehrlich-Institut

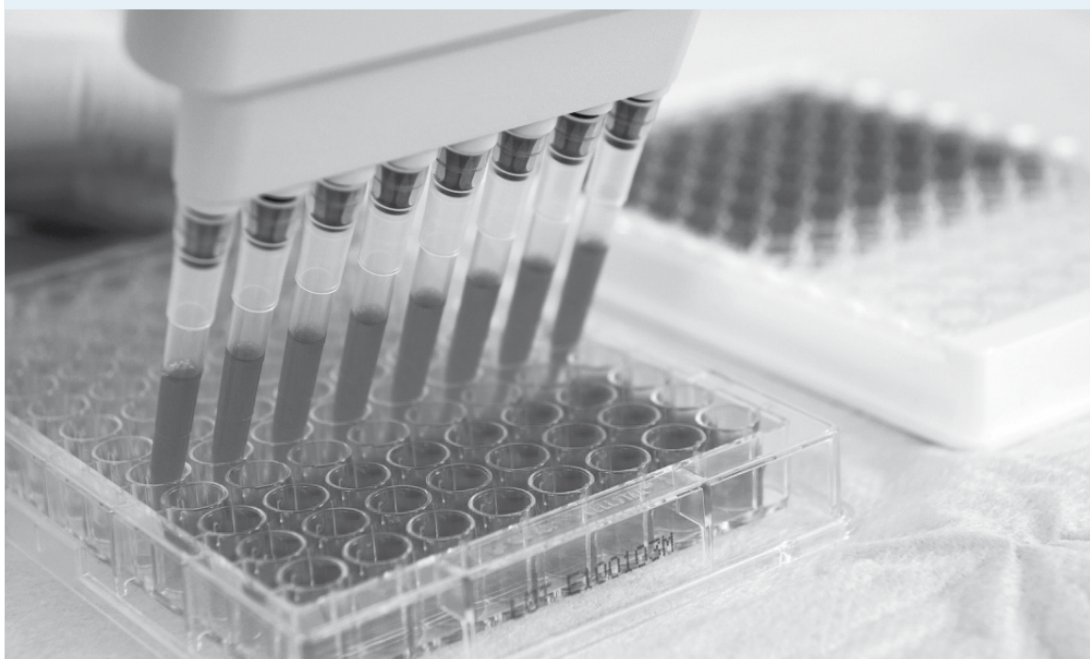


Dr Sandra Stoppelkamp
Universität Tübingen and
South Westphalia
University of Applied
Sciences

Monocyte Activation Test (MAT)

Hands-on Laboratory Training Course

13/14 February 2020 | 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 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.

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

MAT a compendial test method

- Explanation of European Pharmacopoeia 2.6.30
- International status of MAT

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

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

Case study – Cryo blood and Cell-based MAT

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

Monocyte Activation Test: The In-vitro Pyrogen Test Based on Human Immune Cells for Batch Release Testing of Medical Products

- Presenting the MAT as a robust, reproducible, sensitive and human specific pyrogen testing
- An end-to-end process: MAT kit generation, test performance and product-specific validation
- Presenting the solution to the recent EP criteria: MAT as risk assessment for the endotoxin test and replacement of RPT
- The solution for pyrogenicity tests of medical devices

Hands-on training in the Lab

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

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

Measurement of Samples

Case study – PBMC based MAT

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

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

MAT and its challenges

- Variability of test systems
- Interpretation of test results



Presentation and discussion of results

Moderators

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

Speakers

Esther Frey, Novartis Pharma AG | Lab coordinator

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 | Senior Immunology Scientist

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.

Ruth Röder, Microcoat | Project Manager Endotoxin

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

Shabnam Solati, CTL-MAT | CEO

Shabnam studied at the Universities of Groningen and Amsterdam. After nearly 15 years at Sanquin in different research analytical positions, she founded 2017 her own business in the field of Monocyte Activation Testing.

Dr Ingo Spreitzer, Paul-Ehrlich-Institut

Deputy Head of Section 1/3, "Microbial Safety and Parasitology". 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

Universität Tübingen and South Westphalia University of Applied Sciences | Scientist

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.

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:

Reservation Form (Please complete in full)

- Monocyte Activation Test (MAT), 13/14 February 2020, Munich/Bernried, Germany
- Low Endotoxin Recovery/Masking, 11/12 February 2020, 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)

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

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 2 weeks prior to the conference 10 %
 - Cancellation until 1 week prior to the conference 50 %
 - Cancellation within 1 week 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 HEIDELBERG will 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 can-

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 2022).

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, 13 February 2020, 09.00 – 17.30 h,
(Registration and coffee 08.30 -09.00 h)
Friday, 14 February 2020, 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

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 12 February at appr. 19.00 from Munich Airport to Hotel Marina. On 14 February at appr. 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 Course” on 11/12 February in Bernried get a € 200 discount.

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 course. Reservation should be made directly with the hotel. Early reservation is recommended.

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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