EDQM-EPAA Pyrogenicity Event

The future of pyrogenicity testing: phasing out the rabbit pyrogen test

This international conference jointly hosted by the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, and the European Partnership for Alternative Approaches to Animal Testing (EPAA), European Commission, will shed light on how the European Pharmacopoeia is, after 50 years of loyal - but animal-based - service, withdrawing the rabbit pyrogen test (RPT) from its texts. Scientific progress has delivered new and more humane methods (the in vitro monocyte-activation test, or MAT). Together with the EPAA, the EDQM wishes to present how the pharmaceutical world is managing the transition to the MAT and the challenges encountered in the process. This conference will also give participants the opportunity to share their experience of both the RPT and the MAT with your peers, to stimulate widespread interest in the transition and ultimately contribute to ensuring that this major 3Rs initiative is brought to a successful – and global – conclusion.

14-15 February 2023, Brussels, Belgium

PROGRAMME

14 February 2023

08:30-09:00 Registration

Opening session

09:00-09:20 Keynote addresses
Susanna Louhimies, European Commission
Petra Doerr, EDQM, Council of Europe

09:20-09:50 EPAA: Harmonisation of the Three Rs in biologicals: striking the right note
Katrin Schütte, European Commission & Shahjahan Shaid, GSK

09:50-10:20 Pulling the rabbit out of the hat: how the European Pharmacopoeia is tackling the rabbit pyrogen test
Emmanuelle Charton & Gwenaël Ciréfice, EDQM, Council of Europe

10:20 - 10:30 Questions & Answer session

10:30 - 11:10 Coffee break

In-depth exploration of the monocyte-activation test (MAT)

Moderator: Ingo Spreitzer, Paul-Ehrlich-Institute (PEI), Germany

11:10-11:40 European Pharmacopoeia chapter *2.6.30*
Gwenaël Ciréfice, EDQM, Council of Europe

11:40-12:00 An industry-perspective on the validation and implementation of an in-house developed MAT
Ruth Daniels, Janssen, Belgium

12:00-13:30 Lunch break

13:30-14:00 Implementing the MAT, take 2: feedback from a contract laboratory
Johannes Reich, Microcoat, Germany

14:00-14:30 Kit or create: pros and cons of MAT kits versus in-house MAT
Discussion on the two approaches

14:30-15:00 Panel discussion
With the speakers and Eliana Coccia, Italian National Institute of Health (ISS), Italy

15:00-15:30 Coffee break

Pulling the rabbit out of the hat: Industry perspectives

Moderator: Shahjahan Shaid, GSK, Belgium

15:30-16:00 Contract laboratory
Microcoat's experience with the MAT over the last decade
Johannes Reich, Microcoat, Germany

16:00-17:00 Pharmaceutical industry
Pyrogenicity Testing from the Biopharma and Plasma Industry Perspective
Peter Turecek, Takeda, Austria

Comparison of Pyrogenicity Assays for Products Exhibiting Low Endotoxin Recovery
Ned Mozier, Pfizer, USA

17:00 Close of day 1

15 February 2023

Pulling the rabbit out of the hat: Industry perspectives (cont.)

Moderator: Shahjahan Shaid, GSK, Belgium

09:00-10:00 Pharmaceutical industry

Exploiting the monocyte activation test for assessing the pyrogenicity of vaccines: instances from industry
Liliana Alleri, GSK, Italy

Pyrogenicity testing of vaccines: no future for the rabbit pyrogen test
Emmanuelle Coppens and Stéphanie Richard, Sanofi, France

10:00-10:30 Panel discussion

10:30-11:00 Coffee break

Regulatory Session: So what will rabbit-free pyrogen testing look like in Europe? How about the rest of the world?

Moderator: Dean Smith, Health Canada, Canada

11:00-12:00 A European regulator's viewpoint

Phasing out the rabbit pyrogen test - the view from the perspective of antibiotics
Uwe Lipke, Federal Institute for Drugs and Medical Devices (BfArM), Germany

EMAs regulatory science strategy in practice - Regulatory acceptance of 3R testing approaches
Sonja Beken, Federal agency for medicines and health products (FAGG), Belgium

12:00-13:30 Lunch break

13:30-14:30 Pyrogen testing in the USA: past, present and future
Leslie Furr, US Pharmacopeia (USP), USA

14:30-15:00 Pyrogenicity testing recommendations in WHO guidelines
Richard Isbrucker, World Health Organization (WHO)

15:00-15:30 Coffee break

15:30-16:30 Perspectives from other regions

Monocyte Activation Test in the Chinese Pharmacopoeia
Qing He, NIFDC, China

Exploration of the MAT in Japan
Takao Ashikaga, National Institute of Health Sciences (NIHS), Japan

Progress in the regulatory acceptance of MAT in Brazil
Octavio Augusto Franca Presgrave, Fiocruz, BraCVAM, Brazil

Pyrogenicity testing - Indian Pharmacopoeia (IP) perspective
Kalaivani Muthusamy, Indian Pharmacopoeia Commission, India

16:30-17:30 Panel discussion

17:30 Close of day 2

EDQM-EPAA MAT Training Session

Training session organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, and the European Partnership for Alternative Approaches to Animal Testing (EPAA), European Commission

16 February 2023, Brussels, Belgium

PROGRAMME

16 February 2023 (morning only)

Hands on experience, case studies, troubleshooting with technicians from different laboratories

Moderator: Laura Viviani, Independent Consultant, Humane Society International

Trainers:

- Ruth Röder, Microcoat, Germany
- Trusha Desai, NIBSC, Medicines & Healthcare products Regulatory Agency (MHRA), UK
- Marilena Paola Etna, Italian National Institute of Health (ISS), Italy
- Liliana Alleri, GSK, Belgium
- Björn Becker, Paul-Ehrlich-Institute (PEI), Germany
- Ingo Spreitzer, Paul-Ehrlich-Institute (PEI), Germany

09:00-09:10 Welcome and Opening
Katrin Schütte, European Commission & Emmanuelle Charton, EDQM, Council of Europe

09:10-09:50 Qualification of Peripheral Blood Mononuclear Cells (PBMCs)

09:50-10:20 Freezing and thawing of PBMCs

10:20-10:40 Coffee break

10:40-12:00 Cell handling in the MAT assay

12:00-12:15 Coffee break

12:15-12:30 Readout options

12:30-13:00 Round table on the technical topic: Regulatory Acceptance

13:00-13:10 Closure and Goodbye