



The European Partnership  
for Alternative Approaches to Animal Testing



European Directorate  
for the Quality  
of Medicines  
& HealthCare

Direction européenne  
de la qualité  
du médicament  
& soins de santé



COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

## 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 & Gwenaél Ciréface, 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 Ciréface, 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*



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## **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
- Lilliana 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**