Pyrogen testing 2.0: Ethical, Evolving and Eco-friendly

Implementing safe, rapid, state-of-the art and sustainable non-animal approaches worldwide

25-26 February 2026 - European Commission, Albert Borschette Conference Center, Rue Froissart 36, Brussels, and Online

Preliminary Programme *(subject to change)*

Wednesday, 25 February 2026

08:00-09:00: Participant registration

Opening session

09:00-09:15: **Welcome addresses**

- Susanna Louhimies, European Commission
- Petra Doerr, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe

09:15-09:30: **European Pharmacopoeia update**

- Emmanuelle Charton, EDQM, Council of Europe

Session 1: Phasing out of the Rabbit Pyrogen Test (RPT)
Moderator: Emmanuelle Charton

09:30-10:30: **Implementation in Europe: the regulatory perspective**

Including questions raised by stakeholders, procedural aspects and the situation from the perspective of the European Medicines Agency 3Rs Working Party

Questions raised by stakeholders

- Emmanuelle Charton, EDQM, Council of Europe

Procedural aspects

- Phasing out of the rabbit pyrogen test (RPT): Procedural aspects
  Filipa Sameiro, European Medicines Agency (EMA)

Situation from the EMA 3R Working Party

- EMA 3Rs Working Party: Supporting regulatory integration of scientifically valid 3Rs testing approaches
  Sonja Beken, Federal Agency for Medicines and Health Products (FAMHP)

10:30-11:00: Coffee break

epaa The European Partnership for Alternative Approaches to Animal Testing

edqm 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

11:00-12:00: **Implementation in Europe: the industry perspective**

- Validated, QC-compatible pyrogen testing for vaccines: Industry deployment of a reporter-cell monocyte activation test (MAT)
  Siija Yi, Merck
- Advancing sustainable pyrogen testing: Global progress in RPT replacement with non-animal approaches
  Emmanuelle Coppens, Sanofi
- Title to be confirmed
  Shahjahan Shaid, GlaxoSmithKline

12:00-12:30: **Panel session: Has everything been resolved? What hurdles remain?**

12:30-13:30: Lunch break

13:30-14:45: **Situation outside Europe**

Update from regulators and pharmacopoeias outside Europe. Are we all working towards the same goal? What remains to be done to achieve the worldwide suppression of the RPT? How advanced is the implementation of the MAT?

- The International Medicines Regulators' Working Group on 3Rs: Supporting global harmonisation
  Orla Moriarty, International Medicines Regulators Working Group on 3Rs (IMRWG3R)
- Phasing out rabbit pyrogen tests: USP's approach in the United States
  Leslie Furr, US Pharmacopeia (USP)
- Latest progress of pyrogen/endotoxin test in Chinese Pharmacopoeia
  Qing He, National Institutes for Food and Drug Control (NIFDC)

14:45-15:15: Break

15:15-16:30: **Situation outside Europe (continued)**

- The recent changes in the landscape of rabbit pyrogen testing and the planned listing of the monocyte activation test in the general information of the Japanese Pharmacopoeia
  Katsuhiko Hayashi, National Institute of Health Sciences (NIHS)
- Pyrogen testing in Indian Pharmacopoeia (IP): Current status and way forward
  Anil Kumar Toetia, Indian Pharmacopoeia Commission (IPC)
- MFDS's Implementation efforts for alternatives to animal testing
  Hokyung Oh, Ministry of Food and Drug Safety (MFDS)

16:30-17:30: **Panel session: Regulatory alignment: are we close to worldwide phasing out of the RPT?**

Thursday, 26 February 2026

Session 2: Monocyte Activation Test (MAT)
Moderator: Shahjahan Shaid

09:00-10:30: **Implementation of the MAT: validation strategies, technical challenges and success stories**

Implementation in a QC setting

- Optimising MAT through an integrated approach: Rigorous validation, smart automation and strategic dual sourcing
  Stéphanie Richard, Sanofi
- Title to be confirmed
  Shahjahan Shaid, GlaxoSmithKline
- Validation and implementation of a monocyte activation test as a replacement for the rabbit pyrogen test
  Sven Deutschmann, Roche
- From early use to routine QC: The advancement of MAT
  Johannes Reich, Microcoat

10:30-11:00: Coffee break

11:00-11:40: **Implementation of the MAT: validation strategies, technical challenges and success stories (continued)**

- MAT validation strategy assessment
  Barbora Ladinova, State Institution for Drug Control (SUKL)
- Title to be confirmed
  Health Canada representative (to be confirmed)

11:40-12:00: **Developments in the MAT since the EDQM-EPAA 2023 conference: what has happened, technical developments and new validation requirements**

- Developments in the MAT since the EDQM-EPAA 2023 conference
  Ingo Spreitzer, Paul-Ehrlich-Institut (PEI)

12:00-12:30: **Panel session: Are there still issues in implementing the MAT?**
The panel discussion will feature Elliot Lilley, from the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), as one of the speakers.

12:30-13:30: Lunch break

Session 3: Recombinant reagents for Bacterial Endotoxin Testing (BET)
Moderator: Ingo Spreitzer

13:30-14:30: **Experience from industry**

Recombinant factor C (rFC)

- Title to be confirmed
  Shahjahan Shaid, GlaxoSmithKline
- Title to be confirmed
  Catrina Stirling, AnimalHealthEurope

Recombinant cascade reagent (rCR): how close are we to following the same path as recombinant factor C (rFC)?

- Recombinant bacterial endotoxin testing: A generational change
  Jay Bolden, Eli Lilly

14:30-15:10: **Regulatory and pharmacopoeia acceptance of recombinant reagents in Europe and worldwide**

- Regulatory perspectives on recombinant alternatives (rFC & rCR) and their path to European acceptance
  Barbora Ladinova, State Institution for Drug Control (SUKL)
- Position of the Ph. Eur., the USP and the Pharmacopoeial Discussion Group
  Leslie Furr, USP and Emmanuelle Charton, EDQM, Council of Europe

15:10-15:40: Break

15:40-16:40: **Panel session: rFC: what is needed to increase confidence in rFC worldwide? How far to go before regulatory acceptance of rCR? Phasing out limulus amoebocyte lysate (LAL): dream or reality?**

16:40: **Closing of the symposium**