

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



Programme

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*



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)
Sijia Yi, MSD
- Advancing sustainable pyrogen testing: Global progress in RPT replacement with non-animal approaches
Emmanuelle Coppens, Sanofi
- The industry perspective on phasing out of RPT by implementing MAT and BET
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 Teotia, 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: Kirsty Reid, EFPIA

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
- QC requirements for MAT method validation and qualification of PMCS or cell lines
Liliana Alleri, 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)
- Health Canada's perspective on the monocyte activation test: Insights and experiences
Cynthia Allen, Health Canada

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)

- Industry perspective on the regulatory impact of recombinant Endotoxin testing introduction
Abdelmoughit Kaoukab Raji, GlaxoSmithKline
- Experience from Vet industry of working towards replacing LAL with rFC and rCR
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

Katrin Schütte, European Commission

