International Alliance for Biological Standardization

Animal Testing Replacement for Vaccines.
A One Health View: Global Outlook and Future Strategy

December 2-4, 2025
Bangkok, Thailand

Navigating the Transition: Regulatory and Practical Perspectives on Implementing the Monocyte Activation Test

The landscape of endotoxin and pyrogen testing is undergoing a significant transformation as the industry moves away from traditional animal-based methods—such as the Limulus Amebocyte Lysate (LAL) and Rabbit Pyrogen Test (RPT) — toward fully animal-free alternatives. Recombinant bacterial endotoxin tests are increasingly replacing LAL, while the Monocyte Activation Test (MAT) has emerged as the key in vitro alternative to the RPT in Europe.

For decades, the RPT has been the compendial standard for detecting pyrogens in pharmaceutical products. However, in line with global efforts to enhance animal welfare and the principles of the 3Rs (Replacement, Reduction and Refinement), the European Pharmacopoeia (Ph. Eur.) has introduced the MAT, based on human immune cell responses, as the new approach. With Ph. Eur. chapter 5.1.13 now in effect and the complete phase-out of the RPT in the European Union by 2026, the implementation of the MAT as a replacement has become a priority.

This presentation will provide a high-level overview of how companies can navigate this transition. Key topics will include the essential steps for developing and implementing MAT-based strategies—from method development, to validation including risk assessment and QC testing. In addition, we will summarize regulatory requirements, discuss feedback to submissions, and provide practical strategies to meet regulatory expectations. Selected case studies will illustrate real-world experiences, demonstrating a successful path towards the implementation of the MAT.