Providing Sterilisation & Laboratory Services for the world's most innovative healthcare companies.

From the Blog

Innovating Laboratory Testing: New Alternatives to Animal Testing for Medical Devices & Pharma

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At Medistri, we are committed to advancing healthcare through innovation in laboratory and sterilization services. As regulatory standards evolve and global healthcare companies look for faster, more ethical, and more predictive safety assessments, Medistri supports clients in transitioning from traditional animal testing toward validated in vitro and animal-free methods.

This article presents a brief overview of key innovations in biocompatibility and safety testing, with a focus on new alternative methods, regulatory changes, and how Medistri integrates these advances into our laboratory services.

Why Move Beyond Animal Testing?
For decades, animal models have been the reference standard for evaluating the safety of medical devices and pharmaceutical products. However, these tests are often slow, costly, raise ethical concerns, and sometimes fail to accurately predict human responses. In response, regulators worldwide—including the FDA, EMA, and Swissmedic—are encouraging a transition to alternative in vitro and animal-free methods that offer higher human relevance, faster results, and more sustainable practices.

The principles of the "3Rs"—Replacement, Reduction, and Refinement of animal use—now guide regulatory science. Recent updates, like the FDA Modernization Act 2.0, support the adoption of in vitro and computational models, marking a major shift in how safety and efficacy are demonstrated.

Evolving Regulatory Landscape
Medistri's laboratory services are designed to meet the latest international regulations and standards, including:

- ISO 10993 series: Governing biological evaluation of medical devices.
- OECD guidelines: Covering new validated in vitro models.
- European Pharmacopoeia (Ph. Eur.): Recognizing animal-free pyrogen tests.
- United States Pharmacopeia (USP): Expanding acceptance of recombinant reagents and alternative methods.

Key regulatory changes include:

- Full replacement of the rabbit pyrogen test with the Monocyte Activation Test (MAT) in the European Pharmacopoeia as of July 2025.
- Acceptance of recombinant Factor C (rFC) assays for endotoxin testing in both Europe and the USA.
- In vitro irritation and sensitization models: Now validated and accepted in the EU and Asia for local effects; FDA recognition is pending.

Medistri's Commitment: Quality, Innovation & Service
Medistri's ISO 17025 accredited laboratory provides a full spectrum of biocompatibility and chemical safety tests for medical devices, pharmaceuticals, and packaging. Our experts guide clients through:

- Selecting the best validated alternative methods for each application.
- Navigating changing international regulations.
- Delivering reliable results with faster turnaround times and reduced animal use.

We partner with leading manufacturers to shape the future of laboratory testing, integrating the latest scientific and regulatory advances for safer, more sustainable healthcare products.

Alternative Methods: What's New?

1. Endotoxin & Pyrogen Testing
   - Recombinant Factor C (rFC): Animal-free detection of bacterial endotoxins. rFC (full cascade and only rFC) is now fully recognized in Europe and the US, reducing reliance on horseshoe crab blood.
   - Monocyte Activation Test (MAT): Now the gold standard in Europe for pyrogen testing, replacing the rabbit test. MAT directly uses human immune cells, providing higher relevance and sensitivity.

2. In Vitro Irritation Testing
   - ISO 10993-23 & OECD TG 439: Provide validated protocols for skin and eye irritation using reconstructed human tissue models. These in vitro assays are now recognized in Europe and Asia, and acceptance by the FDA is expected soon.

3. Sensitization Testing
   - Integrated Approaches to Testing and Assessment (IATA): Multiple in vitro and in silico assays are combined to predict sensitization risk. These include OECD 497 and advanced computational models, moving towards a future where animal tests are fully replaced.
   - Please note: As of June 2025, sensitization models are NOT yet officially recognized by any major regulatory body. Adoption is still pending and under review.

4. Advanced Human-Relevant Models
   - Organoids & "Human-on-a-Chip": Next-generation systems that replicate complex tissue and organ functions. These technologies promise even higher predictive power for human safety, and Medistri is actively monitoring their regulatory acceptance.

Learn more about our Laboratory. To ensure your products meet the highest quality and safety standards, contact our dedicated team at contact@medistri.com.

— The Medistri Team

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