eurofins | Medical Device Testing

Biological Safety Assessment & Biocompatibility Testing

Choose Eurofins Medical Device Testing to help you:

- ✓ Evaluate the biocompatibility of your new device
- ✓ Assess the impact of a design change or new manufacturing process on your device's safety
- ✓ Evaluate new raw material suppliers
- ✓ Consider effects of sterilization techniques or long-term material stability
- ✓ Generate toxicology reports
- ✓ Establish biological evaluation plans
- ✓ Conduct gap analyses of existing biocompatibility dossiers

Biological Safety Assessments

Eurofins Medical Device Testing is ISO 17025 accredited and has expertise in a wide range of products and manufacturing processes to help assess the biological risks of a new device design or process change and develop an appropriate testing program for assessing the safety of your products.

From chemical characterization of degradation products and extractables and leachables testing, to toxicological risk assessments and biological evaluations, our veterinarians, chemists and toxicologists can facilitate the appropriate testing to best support your international regulatory submissions.

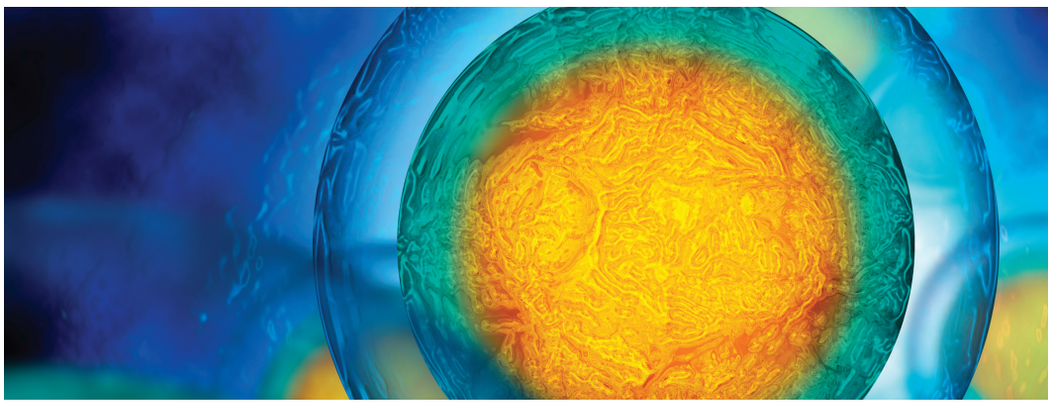
Chemical Characterization

With more than 500 state-of-the art chromatographic analyzers and 5,300 m^3 (187,000 ft^3) of environmental chambers, operated by our global team of highly trained chemists, Eurofins Medical Device Testing provides unparalleled capabilities for all your chemical characterization testing needs, including:

- Chemical Characterization of Materials (ISO 10993-12, 18, 19)
- Identification and Quantification of Degradation Products (ISO 10993-13, 14, 15)
- Determination of Tolerable Intake for Extractable Substances (ISO 10993-17)
- Ethylene Oxide Sterilization Residuals (ISO 10993-7)

Toxicology & Risk Assessment

Our toxicologists perform genetic toxicology assessments, alternative toxicology assessments and toxicological risk assessments based on data from extractable and leachable testing to help you understand the safety profile of your medical device. Based on ISO 10993-17, Eurofins Medical Device Testing will identify and evaluate toxicity risks to humans exposed to the final medical device. Evaluations may also be performed on individual chemical compounds, additives, colorants, processing aids, and other potential leachables. Once identified, Eurofins Medical Device Testing can help to determine if additional analytical testing will be needed to help support your product.



Biocompatibility Testing

Eurofins Medical Device Testing offers the full range of Biocompatibility Testing required by the medical device industry. This includes studies according to the matrix of ISO 10993-1, MHLW requirements, USP classification of plastics (including Class VI), and other international guidelines. We have also established a variety of cell-based alternatives to *in vivo* testing. This testing may be performed GLP or non-GLP based on your needs. The most suitable customized test strategy design is chosen depending on the material of the product, intended use of the product, and the aim of the study.

Cytotoxicity

- Growth Inhibition
- ISO/USP Elution
- Quantitative Cytotoxicity Assays (ex: XTT)
- Direct Cell Contact
- Agar Diffusion Test
- Colony Forming Assay

Hemocompatibility

- Dynamic Test Designs
- Chandler-Loop Design
- Agitation Model
- Static Test Designs
- Hemolysis (ASTM and ISO)
- Platelet Count
- PTT
- Thrombogenity
- Complement Activation

Implantation

- Intramuscular, Subcutaneous Implantation
- Bone Implantation
- Animal Performance Studies
- Customized Efficacy Studies
- Efficacy Studies with Systemic Toxicology

Sensitization

- Maximization Test (Magnusson & Kligman)
- Closed Patch Test (Buehler)
- Local Lymph Node Assay (LLNA)
- *In vitro* Sensitization (hCLAT, DPRA, KeratinoSens)

Irritation

- Dermal Irritation
- Intracutaneous Irritation
- Ocular Irritation
- Oral Mucosal Irritation Test
- Penile Irritation Test
- Rectal Irritation Test
- Vaginal Irritation Test
- *In vitro* Irritation (Episkin and Epiderm)

Toxicity

- Acute Systemic Toxicity
- Systemic Toxicity (Subacute, Subchronic & Chronic)
- Reproductive & Developmental Toxicity
- Inhalation Toxicity
- Carcinogenicity
- Pyrogenicity

Genotoxicity

- Bacterial Mutation - Ames Mutagenicity
- Mammalian Mutation Assay: Mouse Lymphoma Assay
- Chromosome Aberration Test (Chinese Hamster Cell and Human Lymphocyte)
- *In vivo* Micronucleus Assay
- Micronucleus Assay (Chinese Hamster Cell and Human Lymphocyte)

In vivo testing is performed by our partner labs.

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