Biological safety and biocompatibility of medical devices

Eurofins laboratories are ISO 17025 accredited and have the capability to test a wide range of products and manufacturing processes. Our technical experts develop bespoke testing programs, designed to help customers assess the safety and risks of medical devices.

Service scope

- Evaluation of the biocompatibility of your new device;
- Assessment of the impact that a design change or new manufacturing process has on your device's safety;
- Evaluation of new raw material suppliers;
- Consideration of the effects of sterilisation techniques or long-term material stability;
- Generation of toxicology reports;
- Review of the biocompatibility evaluations for your international regulatory submissions;
- Establishment of biological safety plans and execution of gap analyses of existing biocompatibility dossiers.

Biological safety assessments

From chemical characterisation 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 characterisation

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

- Chemical Characterisation 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 risk and toxicological assessments, including genetic toxicology, alternative toxicology and toxicological risk assessments to help you understand the safety profile of your medical devices. Based on ISO 10993-17, our methods identify and evaluate any existing toxicity and human exposure risks associated with the final medical devices, as well as on individual chemical compounds, additives, colorants, processing aids and other potential leachables. Once identified, we use these profiles to determine additional analytical testing needs for further investigations of unknown entities.

Biocompatibility testing

Eurofins offers the full range of Biocompatibility Testing required by the medical device industry. In addition to conducting biological studies according to the matrix of ISO 10993-1, MHLW requirements, USP classification of plastics, including Class VI and other international guidelines, we have established a variety of cell-based alternative methods or models under GLP to examine the hazardous effects of medical devices. The most suitable customised test strategy design is chosen depending on the material of the product, manufacturing methods 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

- Eurofins 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)

Quality Assurance and Control throughout the Supply Chain

Whichever your role in the supply chain you need to safeguard the reputation of your brand and/or that of your client. From supplier's assessment, R&D support, regulatory guidance, supply chain mapping, all the way through compliance and bespoke testing, QC inspections and down to failure analysis or market surveillance, we cover every need of your product's quality journey.