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Medical Device Testing

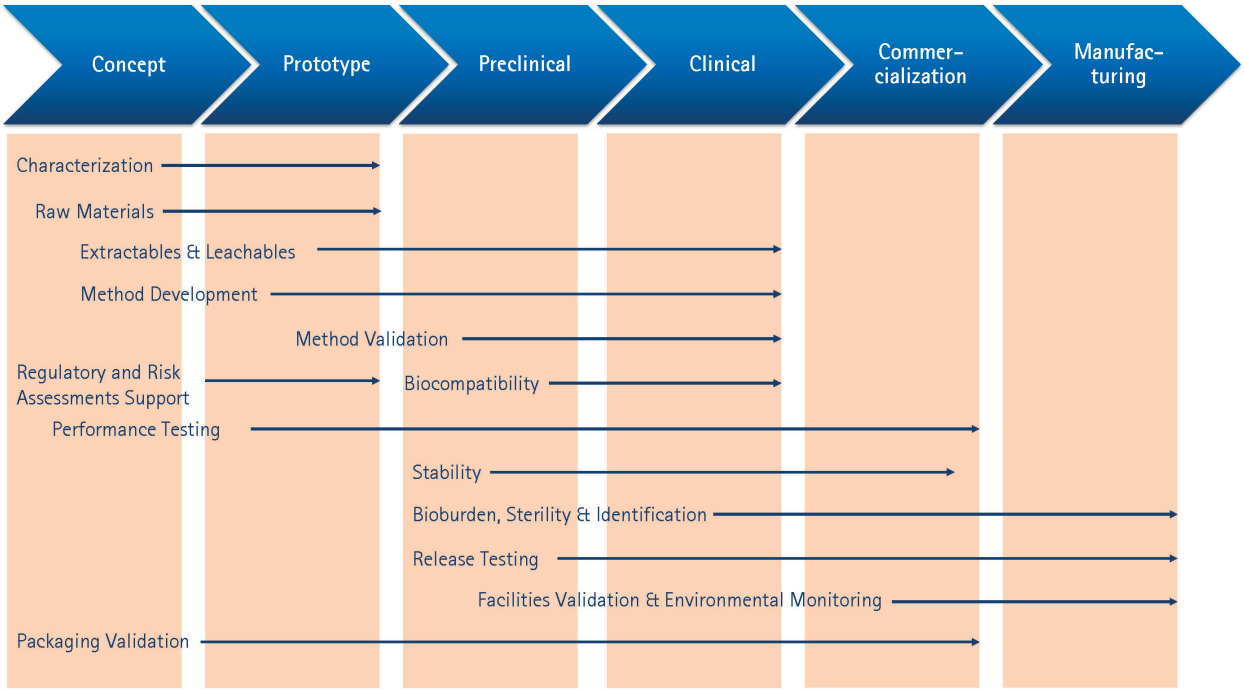
Eurofins Medical Device Testing is a member of the Eurofins BioPharma Product Testing Group— the largest network of medical device testing and harmonized bio/pharmaceutical GMP product testing labs worldwide.

With extensive knowledge of the commercial process, regulatory requirements and scientific trends in the Medical Device Industry, Eurofins Medical Device Testing provides the optimal strategy for Medical Device Companies of all sizes.

Why Choose Eurofins Medical Device Testing?

- Our state-of-the-art global facilities offer extensive laboratory capacity and the highest level of instrument technology, enabling us to provide the full scope of testing services required by the Medical Device Industry.
- Our outstanding regulatory track record, with routine audits by clients as well as several local and international agencies, gives us the expertise to meet the global reporting needs of our clients.
- Our in-depth technical expertise gained through 25 years of work exemplifies our experience with many different types of medical devices.

Eurofins Testing Services for Medical Devices at a Glance



Our Core Philosophy

- Development of an individual and optimal strategy for each medical device based on the risk and toxicological assessment approach
- Apart from standard testing, establishment of tailor-made study designs for special customer requests
- Helping the medical device customers with their individual projects by solving problems of unexpected test results
- Active participation in relevant working groups of e.g., ISO 10993 guarantee best scientific practice and support in medical device testing
- Prime quality in performance of studies and documentation managed by three quality systems for worldwide acceptance of study results

Biological Safety

Chemical Characterization for Materials

As part of the biological evaluation of medical devices, Eurofins Medical Device Testing offers chemical characterization services, as outlined in ISO 10993 Part 18: Chemical Characterization of Materials. While analytical methods and concepts are consistent with extractables and leachables studies for containers and closure systems, quick and affordable solutions are needed for the comparison of medical device products after design and material changes, as well as change of raw material, production lot or aging. To achieve this we utilize the GC/HPLC/ICP fingerprint, a standardized analytical service for existing material and production data leading to complete chemical characterization of medical device products.

In some situations, a customized study outline is recommended to complete the characterization and the safety evaluation of the device. Thanks to our expertise in both medical devices and pharmaceutical packaging areas, we will be able to support you in designing a tailored study protocol (extraction temperature and duration, simulants to be used, etc.) for the analytical evaluation of the extractables and their toxicological assessment.

Our chemical characterization services include:

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

Risk Assessment/Toxicological Assessment

Our Toxicologist will help you to perform risk and toxicological assessments to help understand the safety profile of the medical device product. Such profiles can be used to drive additional analytical testing for further investigations of unknown entities, as well as biocompatibility program strategies or they can be combined with pre-clinical data for a comprehensive risk assessment. These assessments are based on ISO 10993-17 to identify and critically evaluate any existing toxicity and human exposure data on the final medical device product, on individual chemical compounds, additives, colorants, processing aids and potential leachables.

Biocompatibility Testing

Within the Eurofins network of laboratories, we offer 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, FDA Blue Book Memorandum, 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 suitable customized test strategy design is chosen depending on the material of the product, manufacturing methods and the aim of the study.

Our services include standard testing methods, tailor-made studies as well as alternative *in vitro* testing methods or comprehensive histopathological services:

- Cytotoxicity (various cell lines, validation acc. to ICH guidelines)
- Genetic Toxicology (new methods e.g. FACS, Pig-a)
- Hemocompatibility (Static and Dynamic Studies)
- Sensitization
- Irritation and Local Tolerance Tests (various routes of application)
- *in vitro* Test System for Substitution of Animal Models
- Acute Systemic Toxicity
- Pyrogenicity
- Subacute, Subchronic and Chronic Toxicity*
- Implantation*
- Implantation in Combination with Systemic Toxicity*

*combined with comprehensive histopathology

Additionally, we offer certificates, expert statements and toxicological evaluation of the test results, literature and material data. Our clients can be sure that Eurofins Medical Device Testing provides the best test strategy for your medical devices, which is in line with the latest scientific trends.

Bridging Studies

Eurofins Medical Device Testing also conducts bridging studies to determine the scientific background for the biological evaluation of a medical device. Biocompatibility is evaluated through expert reports based on material and literature data, along with actual study results. These studies provide essential information for assessing risks and benefits as well as achieving the ethical conduct of the planned evaluation as required by the animal welfare regulation (i.e., ISO 10993-2).

Microbiological Safety

Eurofins Medical Device Testing also provides a comprehensive range of microbiological services in support of facility and product monitoring, as well as product development and registration. We help clients fulfill special requirements either by standardized test designs or tailor-made studies.

Our microbiological services include:

- Sterility Testing
- Determination of Endotoxins
- Estimation of Bioburden
- Specified Microorganism / Microbial Limit Testing
- Validation of Test Methods
- Identification of Microorganisms
- Antimicrobial Efficacy Testing
- Evaluation of Reusables for the Intended Reprocessing Procedure (Cleaning, Disinfection, Sterilization)
- Environmental Monitoring
- Process Water Testing
- Analysis of Bioindicators
- Validation of Sterilization Processes, including Dose Audits for Irradiation Sterilization
- Validation of Depyrogenation Processes

Physicochemical Evaluation

- Ethylene Oxide Residuals
- Packaging Validations through Accelerated Aging and Sterile Barrier Testing
- Stability Studies and Storage on Raw Materials and Finished Products
- Mechanical Properties and Technical Testing
- Method Development, Validation and Transfers
- Cleaning Validation Analytical Support (TOC, Particle Count, Surfactants Residual, Metals Residuals, etc.)

In-house Training & Seminars

- Training courses accredited to ISO 9001:2008
- High-quality, technical training provided to the Health-care Industry
- Both Open and Customized Training Courses
- Training carried out by internal experts, including study directors, laboratory managers and expert technicians

Quality Standards for Medical Device Testing

Eurofins Medical Device Testing laboratories have been accredited with EN ISO 17025 for biocompatibility testing of medical devices and are certified in accordance with EN ISO 13485, Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP).

Eurofins is listed by the World Health Organization (WHO), has been audited successfully by the Federal Drug Administration (FDA), and is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International for our partner lab in Munich, Germany.

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For more information, please contact us at medical-device@eurofins.com or visit us at www.eurofins.com/medical-devices

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