eurofins | Medical Device Consulting

Medical Device Consulting Services

Our consulting expertise in the field of medical devices allows us to support you for the biological safety of your products. Based on the regulations, actual guidelines and state of the art we develop a test strategy specially adapted to your products and needs which allows you to take advantage of time and costs more effectively and thus achieve the best possible results for registration on inter-/ national market/-s.

In addition we may help you with your production hygiene and sterilization topics as well as with re-processing of your reusables.

We are also happy to train you by attending a workshop at your own facility, by our webinars and/or rather a seminar in our seminar rooms at Eurofins in Munich.

Why Choose Eurofins Medical Device Consulting ?

- 25 years of experience in the field safety testing for medical devices
- Entire network of scientists and experts who will help you with advice and action
- Experts participate in technical committees (DIN, ISO, HAK RDS), in training courses of DGPT, external seminars, internal and external webinars and scientific conferences

Our Comprehensive Services

Eurofins Medical Device Consulting aims to provide you with competent support for your complex tasks.

Biocompatibility of medical devices and combination products

- Global Regulatory Strategy Consulting
- Biological Evaluation Plan and Report (ISO 10993-1)
- Study Validity Verification
- Bridging Assessment e.g. after manufacturing change
- Expert Statements
- Creation of Certificates (ISO and USP)
- Leachable & Extractable Risk Assessment
- Evaluation of Biological and Toxicological hazards
- Management of unexpected Data (Cytotoxicity etc.)

Regulatory Affairs

- Establishment of a technical documentation e.g. according to MDR, 510(k) compiling
- Establishment of a quality system according to ISO 13485

Reprocessing of Reusables

- Support and Optimization of Instructions for Use
- Risk Analysis
- Development of a Testing Strategy
- Support with Unexpected Results

Packaging, Stability and Shelf Life

- Support in Choosing Packaging Material and Configuration
- Regulatory Support
- Develop Testing Strategy for Packaging Validation
- Planning of Stability Testing over Shelf Life
- Determine necessary End Points(physico-chemical Parameters, Biocompatibility, Microbiology, Functionality etc.) to be tested over Shelf Life
- Support with Testing Result

Eurofins Training Academy

- In-house training
- In-company training
- Webinars
- Guideline updates

Consultancy Services

Regulatory • Quality Assurance • Risk Assessment • Technical Documentation

Trainings & Seminars • Biological & Toxicological Risk Assessment

Flexible Service Models

Fee For Service (FFS)

Full-Time-Equivalent (FTE)

PSS Insourcing Solutions®

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