eurofins | Medical Device Consulting



Consulting Services for Reprocessing of Reusables

Requirements for the reprocessing procedures and instructions as well as for the validation studies have been increased for reusables in Europe with publication of the MDR and FDA issuing new guidance and international guidelines permanently.

Our consulting expertise in the field of medical devices and especially reusables allows us to support in creation and optimization of the instructions of use in regard to the reprocessing procedure of your products. Additionally, 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.

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 Consulting in Munich.

Why Choose Eurofins Medical Device Consulting?

- 25 years of experience in reusable products and reprocessing in regard of optimization of the reprocessing procedure and relating testing strategy
- Entire network of scientists and experts who will help you with advice and experts participating in technical committees (DIN, ISO, HAK RDS), external seminars, internal and external Webinars and scientific conferences

Reprocessing of Reusables

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

Regulatory Affairs

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

Biological Evaluation of Medical Devices

- Global Regulatory Strategy
- Biological Evaluation Plan and Report
- Biological Risk Assessment
- Study Validity Verification
- Toxicological Evaluation of Leachables and Extractables
- Bridging Assessment e.g. after Manufacturing Change
- Creation of Certificates e.g. ISO and USP studies

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

Any Questions? Contact Us:
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Our Services at Eurofins Munich:

BioPharma Product Testing
Medical Device Testing
Medical Device Consulting
Human Safety Testing
Professional Scientific Services - Insourcing

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Your Consulting and Training Service for the Medical Device Industry