



Fraunhofer

ITEM

FRAUNHOFER INSTITUTE FOR TOXICOLOGY AND EXPERIMENTAL MEDICINE ITEM

TRANSLATIONAL BIOMEDICAL ENGINEERING



FROM IDEA TO SAFE MEDICAL DEVICE

Development and conformity assessment of medical devices is a complex process subject to stringent regulation under the European Medical Device Regulation (MDR). In this environment, we offer our expertise and conduct R&D projects as well as device testing to prepare for clinical trials. Our focuses are on neural implants and administration of medical aerosols.

Due to our wide network of development partners from industry and academia, we are able to quickly respond to project-specific requirements. We can thus comprehensively assist our clients in the medical device development process, including biocompatibility evaluation (ISO 10993). With regard to quality management and risk management (ISO 13485 and 14971), we also provide regulatory support in the qualification of external technology processes

and the assessment of medical device safety right up to preparation of the design dossier.

Key topic

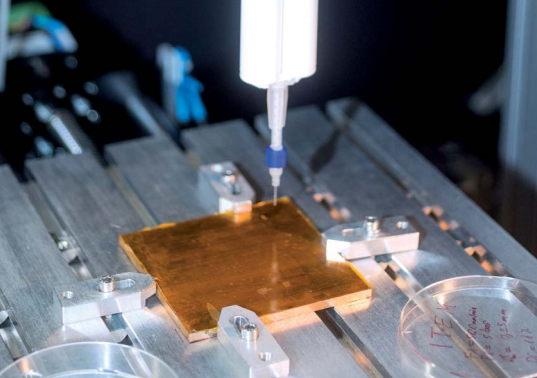
In translational biomedical engineering, we pool our expertise in medical devices with our long-term experience in chemical risk assessment, nanomaterials, and biocompatibility. Medical device manufacturers will get optimal support in their development of MDR-compliant new products and in making adjustments to existing products to comply with MDR requirements.

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*Newly developed method:
individualized implants can be
produced by 3D printing of
medical-grade silicone rubber.*

Our services and expertise

- Development of devices and manufacturing processes to meet the requirements for being used in first clinical trials or for validated test systems
- Implant research and development
 - 3D printing of medical-grade silicone rubber for manufacturing of individualized implants
 - Development of advanced cochlear implants and brain-computer interfaces
 - Development of actuator implants that interface directly with the target tissue
 - Testing and test bench development according to DIN EN ISO 10993 and 14971
 - Accelerated life cycle testing, also for polymer materials
 - Efficacy testing and development of new implant coatings
- Systems and formulations for inhalation therapies
 - Breath-activated aerosol administration; nebulizer development
 - Test methods enabling selection of the optimal inhaler
 - Administration of aerosolized drugs in children, infants, and preterm neonates
 - Development of test benches for new aerosol generators in compliance with the relevant standards (e.g. DIN EN 13544-1, ISO/FDIS 27427)
 - Development of aerosol humidification systems for high-dose dry-powder drug inhalation therapies
 - Development of non-target sensors and cleaning technology for breathing air
 - Clinical trials

- Regulatory support
 - Development of a regulatory strategy for conformity assessment
 - Safety and risk assessment of medical devices (incl. combination products)
 - Support in developing new products or adjusting existing products to comply with MDR requirements

Your benefits

- Collaboration with a partner having regulatory experience with the translation from research to clinical application
- One-stop shop for early-phase development support, documentation, and (product-specific) testing
- Shorter development phases and faster market entry by eliminating the need for downstream testing
- Long track record of working in compliance with GXP guidelines, with synergies of experimental toxicology, advanced analytical methods, and modeling and simulation capabilities
- Close collaboration with universities and testing facilities, in particular via the High-Performance Center Translational Biomedical Engineering

Fraunhofer Institute for Toxicology and Experimental Medicine ITEM

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The Fraunhofer Institute for Toxicology and Experimental Medicine ITEM is one of approximately 70 institutions of the Fraunhofer-Gesellschaft, Europe's leading organization for applied research. Protecting man from health hazards in our industrialized world and contributing to the development of novel therapeutic approaches are the aims Fraunhofer ITEM is pursuing with its contract research, with a focus on airway research.

In the field of translational biomedical engineering we assist our clients in medical device development including conformity assessment and preparation of the technical dossier. If required, we develop new test benches and support safety assessment and the qualification of external technology processes in compliance with the European Medical Device Regulation (MDR).