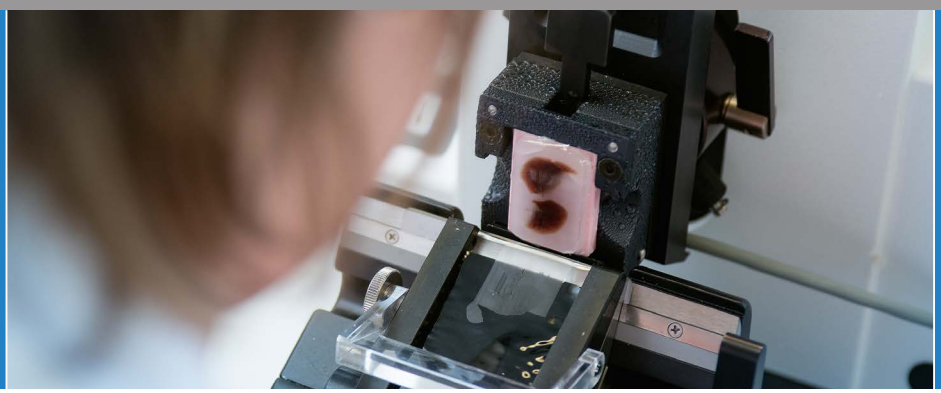
Fraunhofer
ITEM

FRAUNHOFER INSTITUTE FOR TOXICOLOGY AND EXPERIMENTAL MEDICINE ITEM

CHEMICAL SAFETY AND ASSESSMENT



TOXICOLOGY TESTING

Helping to protect man and the environment

We are committed to protecting human health with regard to pharmaceuticals and environmental pollutants and to helping assess and manage potential risks – by using our expert knowledge in toxicology.

We offer our clients a broad range of toxicological tests enabling assessment of potential hazards to human health. Substances we investigate include chemicals, particles, complex mixtures, and nanomaterials. The focus is on inhalation toxicology and on characterizing inhalable substances. Our expertise ranges from the development and implementation of testing strategies to accompanying and providing consultancy to companies in registering their products. A sound basis for our work is provided by the institute's expertise in inhalation, fiber and particle toxicology, and in aerosol research and chemical analysis.

Key topic

We provide consulting and support to our clients in selecting the most appropriate study design, develop concepts for registration and authorization of products, and conduct toxicological studies with different routes of administration, depending on the client's specific needs and requirements. Our focus is on inhalation toxicity testing.

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Electron microscopy is essential in characterizing nanoparticles and nanofibers.

Our services and expertise

- Regulatory assessment by standard toxicology testing in compliance with international guidelines (OECD, EU, EPA, or FDA):
  - Subacute, subchronic, chronic, and carcinogenicity studies
  - Studies in juvenile animals
  - Genetic toxicology
  - Pharmacokinetic and toxicokinetic studies (ADME in vivo and in vitro)
  - Histopathology
  - Immunotoxicological investigations
  - Testing for respiratory irritation (Alarie test)
- Focus inhalation toxicology:
  - Nose-only and whole-body exposure of rodents
  - Toxicokinetics of inhaled particles
  - Specific lung toxicity measurements incl. bronchoalveolar lavage
  - Inflammatory reactions in the lung
- Focus (nano)particles and fibers:
  - Deposition and retention
  - Particle clearance by using radio-labeled tracers
  - Biopersistence of fibers
  - Bioavailability of metals from solid material particles
- Characterization of molecular mechanisms of action
- Toxicological databases (RITA, goRENI, *Dev*Tox)
- P.R.I.T.® ExpoCube® system for in-vitro exposure of cells or tissues to airborne, soluble, and particulate test substances at air/liquid interfaces

Your benefits

- Comprehensive consulting and support throughout the registration and authorization process
- For the authorization of biopharmaceuticals, we develop tailored concepts with specific testing strategies and discuss these with the competent authorities
- Access to a broad range of methods, special methods, and validated test systems and models
- By serving as advisors in various committees, we are always up to date on changes in the relevant guidelines
- As a non-university research institution we can be your partner in applying for public funding

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The Fraunhofer Institute for Toxicology and Experimental Medicine ITEM is one of about 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 area of chemical safety we assess the risks from potentially harmful substances and support the development of novel products with an eye on human health and the environment. We can draw upon a broad spectrum of expertise, covering toxicology testing, exposure assessment, analytical methods, regulatory research, and chemical risk assessment.

From compound to safe products