Scope of our services

Selected studies (as examples):

- Effects and toxicity of plant extracts
- Influence of pharmaceuticals on induction or inhibition of CYP450 monooxygenases
- In-vitro toxicity of inhalable gases
- In-vitro toxicity of nanoparticles (carbon black, carbon nanotubes)
- Cytotoxicity and genotoxicity of quartz-containing ceramic dusts
- Cytotoxicity and genotoxicity of novel antimicrobial preservatives for cosmetics
- In-vitro effects of electromagnetic fields
- Toxicokinetics and genotoxicity of a mycotoxin
- Validation studies in cooperation with regulatory authorities
- Cooperation partner in EU projects (e.g. SEAWIND, ARIMMORA, ACTICOSPACK, SILICOAT, PHOENIX)

The Fraunhofer ITEM offers contract research in the area of human health. The focus of research is on issues of preventive medicine, investigation of novel diagnostic methods and innovative therapeutic concepts, toxicological research, pre-clinical and clinical registration trials.

Contacts

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The Department of In Vitro and Mechanistic Toxicology offers a broad range of in-vitro test methods required for pre-clinical testing of pharmaceutically active ingredients. These tests are equally needed to assess the cytotoxic and genotoxic potentials of environmentally and occupationally relevant substances. The range of available methods also includes alternative test methods in line with the current European chemicals policy (REACH).

Selection of the appropriate cellular test systems and development of the study design is performed in consultation with the sponsor, governed by a variety of criteria such as relevance of the species, organ, and target site, endpoints to be analyzed, compliance with the relevant guidelines (e.g., OECD), and any additional requirements.

**Competences**

- In-vitro exposure of cellular test systems, for example to gases, aerosols, and complex mixtures
- Determination of multiple parameters in cells
- In-vitro ADME assays (e.g., CYP450 monoxygenases, NAT profiling, biochemical parameters)
- Characterization of molecular mechanisms of action
- Regulatory assessments by means of standard genotoxicological tests in compliance with international regulations (OECD, EU, EPA, FDA, ICH)
- GLP certification for toxicological studies according to the German guideline ChemVwV-GLP No. 5.3/OECD (including genotoxicity studies and molecular toxicological studies)
- Cooperation in and coordination of national (BMBF, BfArM, BfR, BfS, UBA) and European (EU, EFSA, ECVAM) publicly funded projects

**Methods**

**Biological test systems**

- Primary cultures of human and animal origin, immortal and transgenic cell lines, co-culture systems, precision-cut liver and lung slices, microsomes

**Exposure**

- Liquid or soluble test substances
- Particulate substances in suspensions
- Airborne test substances (gases, aerosols, particles) in the patented culturing and exposure system P.R.I.T.®-ALI

**Detection of biological effects**

- General toxicity
  - e.g., cytotoxicity, apoptosis, oxidative stress, proliferation, ATP status, interleukins, DNA damage, transcription factors
- Genotoxicity, mutagenicity
  - e.g., comet assay, micronucleus assay, chromosomal aberration test, mouse lymphoma assay
- Molecular mechanisms
  - e.g., expression of toxicologically relevant genes including analysis of specific pathways and transcriptome analyses, epigenetics, and DNA analyses