Fraunhofer
ITEM

FRAUNHOFER INSTITUTE FOR TOXICOLOGY AND EXPERIMENTAL MEDICINE ITEM

DRUG DEVELOPMENT

REGULATORY RESEARCH AND RISK ASSESSMENT

Evaluating and assessing the risks and benefits of innovative medicinal products

Fraunhofer ITEM has combined its expertise in drug research and development with its experience in registration and risk assessment of chemicals. With these forces joined, the institute is uniquely positioned to support clients with regulatory affairs in the drug development process. Our scientists explore, develop, and validate new approaches to manufacture, characterize, and test innovative medicinal products. They furthermore ensure regulatory input on these approaches and implement them in product development in cooperation with the client.

Key topic

Our expertise allows experimental studies for risk assessment and registration of pharmaceuticals to be goal-oriented and focused on what is really needed. We support our clients in regulatory affairs and risk assessment of their medicinal products.

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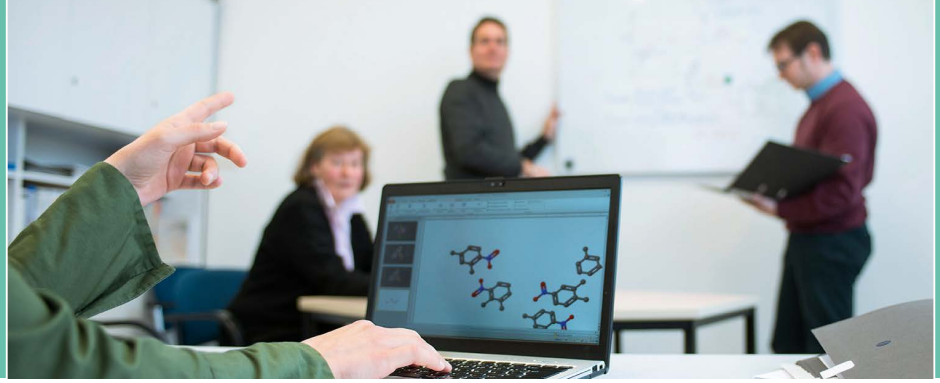

Regulatory research is part of the expertise of Fraunhofer ITEM.

Our services and expertise

- **Preparation of a regulatory strategy:**
  Project planning focusing on regulatory compliance, integration and cross-linking of different R&D disciplines, regulatory troubleshooting and addressing of regulators' concerns

- **Interaction with regulatory authorities:**
  Scientific and regulatory advice meetings with authorities (e.g. national competent authorities, EMA, FDA), application for authorization of clinical trials (national authorities, ethics committee), ATMP classification and certification, application for orphan drug designation, access to EMA's "PRIoritiy MEdicines" (PRIME) scheme and FDA's "breakthrough therapies"

- **Preparation of the required documentation:**
  Study reports in formats acceptable to the regulatory authorities, support in dossier preparation (e.g. IMPD, CTD), core documents according to ICH E6 (e.g. IB, CTP)

- **Risk assessment:**
  Risk-based approach in development, including ATMPs (e.g. according to Directive 2001/83/EC), classification regarding maximum residue limits according to Regulation (EU) No. 37/2010, impact assessment and preparation for new procedures (e.g. Regulation (EU) No. 536/2014, ICH E6R2), environmental risk assessment for GMOs according to Directive 2001/18/EC, environmental risk assessment according to EMEA/CHMP/SWP/4447/00 (strategic planning, risk analysis, study performance and monitoring, revision)

- **Regulatory research:**
  Development of new tools, standards, and approaches for assessment of regulated products, critical path research along the development process

Your benefits

- We act as interface between clients and regulatory authorities, actively participate in panels preparing legislation, and collaborate with national and international scientific organizations.

- The project-specific regulatory team is recruited within Fraunhofer ITEM:
  - Scientific experts in drug development from in-house development platforms (process development and manufacturing of biopharmaceutical investigational medicinal products, non-clinical testing, and clinical trials)
  - Regulatory experts
  - Risk managers

- Involvement of expertise tailor-made to the specific requirements of drug development

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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 drug development, we develop and test novel medications for treating respiratory diseases – in particular asthma, allergic rhinitis, chronic obstructive pulmonary disease (COPD), idiopathic pulmonary fibrosis, and infections. Our expertise ranges from the manufacturing of investigational biopharmaceuticals to preclinical and clinical development.

From drug candidate to proof of concept

- Development and manufacturing of biologics
- Regulatory research and risk assessment
- Preclinical testing
- Clinical trials