Fraunhofer
ITEM

FRAUNHOFER INSTITUTE FOR TOXICOLOGY AND EXPERIMENTAL MEDICINE ITEM

DRUG DEVELOPMENT

DEVELOPMENT AND MANUFACTURING OF BIOLOGICS

Developing your idea into a sterile IMP in a seamless process

Fraunhofer ITEM has more than 25 years of experience in bioprocess development and in GMP manufacturing of biopharmaceutical active ingredients (APIs) and investigational medicinal products (IMPs) for clinical trials. A multidisciplinary team of biologists, chemists, pharmacists, engineers, and technicians assists and leads you on your way from the idea for a new biotherapeutic via the development of a production cell line to the manufacturing and release of an IMP. Depending on your requirements, our services can cover either the complete process or only individual phases. As a Fraunhofer ITEM client, you will benefit from competences and expertise accumulated over years in a broad range of projects on biotherapeutics – from recombinant proteins and glycoproteins to complex multimolecular structures such as viruses and cells. We provide you with the API and IMP and will guide you through the regulatory requirements to an approved IMP dossier for your drug candidate.

Key topic

We aid you on your way from the idea for a new biotherapeutic via development of a production cell line to GMP manufacturing of the IMP released for use in clinical trials.

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Cultivation of recombinant animal or microbial cell lines.

Our services and expertise

- Technical and regulatory consultancy for biopharmaceutical development projects, in particular on recombinant proteins and antibodies
- Engineering of recombinant mammalian and microbial production cell lines
- Cell banking and storage of master and working cell banks
- Development and upscaling of upstream and downstream sequences up to a cultivation volume of 400 liters
- GMP manufacturing and release testing of investigational APIs
- Aseptic filling and release testing of IMPs (liquid dosage forms)

Your benefits

- Fraunhofer ITEM is embedded in a sustainable network of trusted partnerships, both internal and with external agency-approved service providers. Fraunhofer ITEM stands for professional access to state-of-the-art technologies that you need for your candidate biotherapeutics.
- Fraunhofer ITEM is in close contact with the regulatory agencies from the very beginning of your project. We assist you in consulting and scientific advice meetings with the competent authorities such as Paul Ehrlich Institute (PEI) and the German Federal Institute for Drugs and Medical Devices (BfArM).
- Preclinical development as well as clinical trials can be performed in other Fraunhofer ITEM departments, which are embedded in the same quality network. We can offer streamlined and sustainable project approaches.
- You will benefit from Fraunhofer ITEM's comprehensive experience in a broad range of molecules and processes, gained in numerous projects on biotherapeutics. Our track record includes proteins, glycoproteins, a large diversity of antibodies, antibody fragments, bispecific antibodies, BiTEs, virus-like particles, bacteriophages, nucleic acids, and plasmids.
- A clean-room facility for aseptic fill and finish of vials and ampoules has been operational since 2015, enabling production of ready-to-use sterile IMPs and other small batches of up to 3000 units.

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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