Fraunhofer
ITEM

FRAUNHOFER INSTITUTE FOR
TOXICOLOGY AND EXPERIMENTAL
MEDICINE ITEM

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.

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PHARMACEUTICAL BIOTECHNOLOGY

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In an internationally rare combination, the Fraunhofer Institute for Toxicology and Experimental Medicine ITEM covers all the expertise required for the development of novel biopharmaceuticals: from the identification of the active ingredient (API) to the manufacturing of investigational drug products and to clinical trials phases I and II. The necessary GXP quality assurance systems – GLP, GMP, and GCP – have been certified by the drug regulatory authorities for many years.

The Division of Pharmaceutical Biotechnology develops manufacturing processes for biopharmaceutical APIs and provides pilot batches and investigational drug products in compliance with international GMP requirements.

Since 1997 already, the Division has been holding a license according to § 13 of the German Drug Act for the manufacturing of biopharmaceutical APIs. Manufacturing processes for a variety of API candidates have since been developed and investigational drug products have been manufactured in compliance with GMP requirements. For these activities, the Division has at its disposal process development laboratories, pilot plants, and GMP clean-room facilities. The equipment includes bioreactors of up to 500 liters volume as well as process equipment for chromatography and filtration.

At the end of 2008, regulatory approval was received for a new pilot plant allowing production of biopharmaceutical APIs in compliance with the requirements of both European (EMEA) and US standards (FDA).

Biopharmaceutical API targets include recombinant proteins, glycoproteins, DNAs, viruses, and bacteriophages. The production organisms used are common animal cell lines (CHO, BHK), *E. coli* strains, and yeasts, but also less common organisms such as *S. aureus* or insect cells.

Early in 2010, the Division of Pharmaceutical Biotechnology received a GMP license for its newest extension: a Class 100 suite for aseptic fill and finish operations complying with Annex 1 of the European GMP Guideline. This previously missing link now enables to perform all steps of the pharmaceutical development chain at the Fraunhofer ITEM, from early development right up to GMP manufacturing of final dosage forms ready to be used in clinical trials.

Services

– Cell bank manufacturing and storage
– Development of API manufacturing processes (USD, DSP)
– Process validation
– Purification validation
– Development and validation of analytical methods
– Stability testing of intermediate purified bulk and final dosage forms
– GMP- and non-GMP manufacturing of APIs
– GMP manufacturing of liquid investigational medicinal products for clinical trials

Methods

– Cultivation in bioreactors of up to 500 liters capacity
– Organisms: Bacteria: *E. coli, S. aureus*
  Yeasts: *S. cerevisiae, P. pastoris*
  Animal cells: CHO, BHK, NS0, SF9, Hi5
– Analysis of cell culture media
– Cell metabolic testing
– Development of process control strategies (batch, fed-batch, perfusion)
– Process chromatography and filtration
– Release testing for APIs and final dosage forms