


INNOVATION

through

SERVICE

Pharmedartis

a spin-off of  **Fraunhofer**
IME

... one of the largest research organizations in the world
with an annual budget of well over 1 billion US\$

Besides our own research on Immunotherapeutics we offer several innovative services

For your business: **REACT & CARE**

REsearch

Molecular Cloning

- Cloning
- Sequencing
- Mutagenesis
- Transcription analysis
- Differential display

Antibodies

- Construction and screening of phage display libraries
- Generation of full-length monoclonal antibodies
- Construction of antibody-fragments
- (Fluorescence)-labelling of proteins (antibodies)
- Innovative immunization technologies
- Fusion proteins
- ELISA construction

Analytcs

Analytical Standard Techniques

Standard & Sophisticated Methods, e.g.

- Electrophoresis (IEF, PAGE, 2-D-DIGE)
- Chromatography (e.g. RP-LC, GC, gelfiltration)
- Peptide mapping
- ELISA

Sophisticated Technologies (selection only)

- Microarray technology
- 3-Dimensional imaging
- Confocal microscopy
- Radioisotope image detection
- High-throughput cell screening

- Protein crystallography
- Electrospray MS, MS/MS protein identification
- Thermal analysis

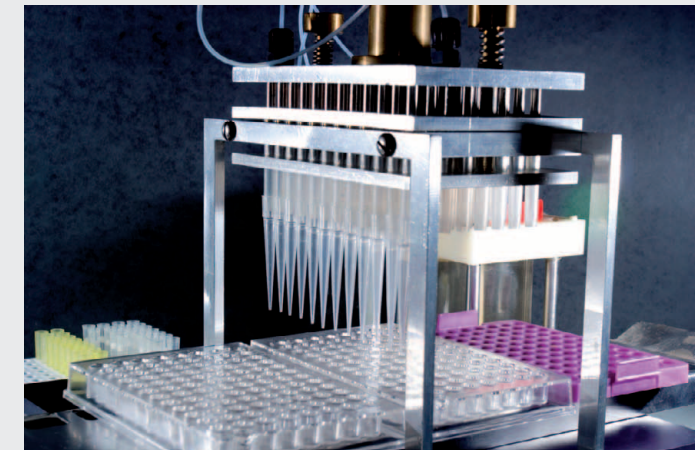
Consulting

- GMP consulting
- Regulatory intelligence and support (e.g. for preparation of CMC-part)
- Sterile manufacturing technology
- Viral safety
- Support in market analysis and commercialization

Technology

Feasibility Studies

- Selection of the strain from a broad spectrum of production systems (bacteria, yeasts, mammalian cells)
- Optimization of the strain and the fermentation conditions
- Development and optimization of the downstream processing (purification)



Production and characterization of Biotechnological APIs

Expression Systems

- Bacteria: e.g. *E. coli*.
- Yeasts: *Hansenula polymorpha*, *Pichia pastoris*, *Arxula adenivorans*, *Saccharomyces cerevisiae*, *Yarrowia lipolytica*
- Mammalian cells: e.g. CHO, HEK293

Process Technologies

Up-stream Processing

- Batch, Fed-batch, Perfusion processes

Down-stream Processing, e.g.

- Chromatography (e.g. AEX, CEX, IMAC, Protein A, gelfiltration)
- Virus inactivation and removal
- Filtration



GMP Facility

Multipurpose facility: 600 sqm (plus storage area), cleanrooms (classes A in C, C & D)

Capacities

- GMP and Non-GMP Fermentation
- 2 Production lines of 100 to 350 L
- 9 Bioreactors of 1 to 30 L
- 16-fold parallel Bioreactor

GMP Manufacturing

- Up-stream and down-stream processing of APIs for use in clinical studies
- Implementation and conduction of a GMP production process

Quality System and Quality Operations

- Definition and realization of the adequate quality system
- Implementation of the quality assurance measures
- Use of a broad palette of chemical and biochemical quality control methods
- Responsibilities of the Qualified Person (e.g. batch release, fulfillment of requirements, product quality review)

Interested?

We welcome working with you, prepare answers and solutions tailor-made to your needs. From the very beginning you will have only one primary contact person to address all your specific matters.

Please visit us and have a look around the Fraunhofer IME, one of the leading Research Institutes in Germany. Please contact us at:

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