CORE COMPETENCY

for

Contract Manufacturing

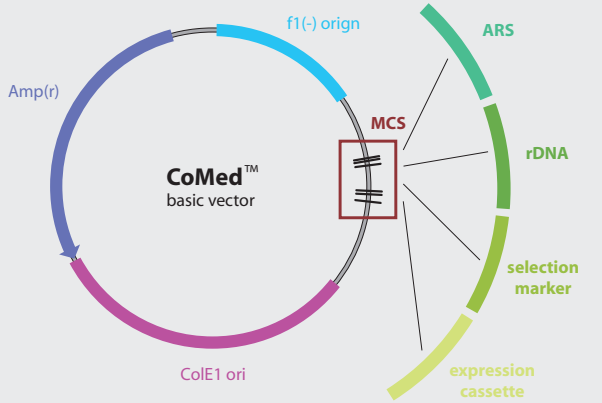
Pharmedartis

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$

Process Development

- Selection of the most suitable expression system
- Proprietary production systems
- Evaluation of different media components and optimization with regards to yield, growth characteristics as well as costs
- Optimization of all fermentation parameters
- Development of the purification process
- Conduction of feasibility studies up to 350 L of working volume



Patent-No.: EP1 698 702 A1 - recombinant protein expression system

Project Management

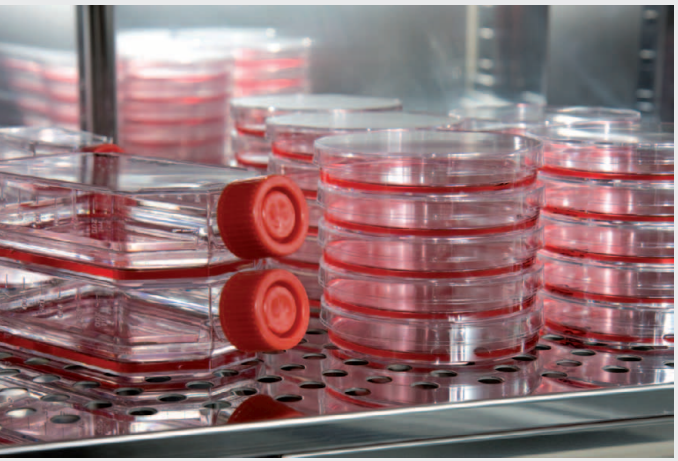
- Definition of all technical and scientific steps necessary for the development of the production of recombinant proteins such as technical enzymes
- Definition and pursuit of all technical development steps for biotechnological Active Pharmaceutical Ingredients (APIs) used in pre-clinical and clinical studies
- Support with regards to general regulatory issues
- Support in market analysis and commercialization

Production

- Production and characterization of Master and Working Cell Banks
- Multipurpose facility: 600 sqm (plus storage area), cleanrooms (classes A in C, C & D)
- 2 Production lines of 100 to 350 L
- 9 Bioreactors of 1 to 30 L
- 16-fold parallel Bioreactor
- Establishment and conduction of the complete GMP up-stream production process up to 350 L working volume. A broad range of established systems from bacteria over yeast to mammalian cells is available
- Establishment and conduction of the complete GMP down-stream process using a wide-range of appropriate state-of-the-art equipment (e.g. AEX, CEX, IMAC, Protein A, gelfiltration), virus inactivation and removal as well as filtration
- Materials handling
- Storage (even long-term) of APIs
- Support for drug formulation studies

Quality Control

- Usage of a wide range of standard chemical and biochemical methods:
  - Electrophoresis (IEF, SDS-PAGE, native PAGE, 2-D-DIGE)
  - Chromatography (e.g. RP-LC, gelfiltration, GC)
  - Peptide mapping
  - ELISA
  - Mass spectrometry
- Development and application of innovative analytical procedures, such as specific mass spectrometry techniques or thermal analysis
- Development of new biological assays
- Conduct of established biological assays



Quality and Quality Assurance

- Definition and realization of the adequate quality system for the customer
- Implementation of the quality assurance measures tailored to the customer's project needs
- Management of daily quality operations
- Realization of an optimized CMC

Qualified Person

Pursuing the responsibilities of the Qualified Person, e.g.:

- Implementation of the batch release process
- Fulfillment of the regulatory requirements for batch release
- Certification of each batch
- Product Quality Review

cGMP Consulting

- Support with regard to the international regulatory requirements (law, regulations, directives, guidelines)
- Definition of a GMP quality system
- Definition and realization of the GMP project requirements
- Viral inactivation and removal
- GMP consulting in engineering projects (GMP concept, qualification, validation)

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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