Contract Development and GMP Manufacturing Services

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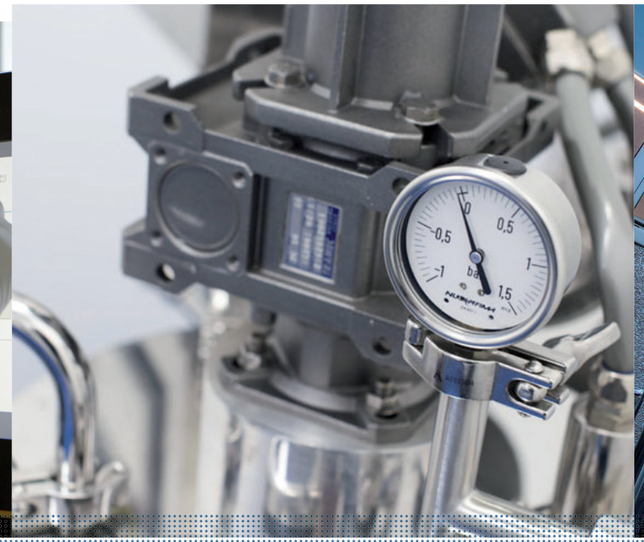

Your partner in biologics production

At Diatheva we provide customized services for the production of microbial-based biopharmaceuticals. We are well positioned to efficiently and expertly support your entire project at all stages of biopharmaceutical development, from cell line generation through process development.

In our state-of-the art GMP production facility authorized by EMA we produce and release biological Active Pharmaceutical Ingredients (APIs) for preclinical and Phase I/II clinical trials.
Our team from lab to pilot & from pilot to production is dedicated to deliver a full service to our partners, striving to tailor unique solutions that fit our clients' needs, bringing their products to market faster.

We work to stringent quality control and the highest level of international regulatory compliance.

Our manufacturing capabilities at a glance:
- cGMP multipurpose production unit (2200 m^2)
- Master and Working Cell Bank production suite
- cGMP manufacturing at up to 200 L fermentation
- Bioprocess modular chromatography system up to 60 L/h for purification step
- State-of-the-art quality control laboratory
- Active Pharmaceutical Ingredient testing and release

We offer

Contract Development Service

Cell line development and characterization
- **Gene & vector optimization**
  Gene cloning
- **Cell line development**
  Escherichia coli expression vector optimization
- **Cell line characterization**

Process development
- **Process development & scale-up**
  Media optimization
  Process development
  Scale-up & optimization
- **Technology transfer**
  Gap analysis
  Feasibility assessment
  Process design

Analytical method development
- **Analytical method development**
  Protein characterization
- **Analytical method validation**

Formulation development
- **Formulation study**
  Pre-formulation study
  Formulation study
  Comparative stability study

Contract Manufacturing Service

Cell bank production
- **Production and characterization of Master Cell Bank**
- **Production and characterization of Working Cell Bank**

Biopharmaceutical APIs production
- **Microbial fermentation**
  20 L-200 L fermentation line
  Tangential filtration harvesting systems
  Cell disruption system
- **Purification**
  Large scale purification chromatography systems
  Ultra-filtration skids

Quality control testing
- **Raw material test**
- **Lot release test**
- **Stability test**

WHY US?

- **Rigorous quality.** AIFA (Italian Medicines Agency) authorized for APIs production
- **Scalability**, capable of efficiently manufacturing biologics of any batch size, from milligrams to multi-grams
- **Full service** offering
- **Experienced team**, strong project management is an important component of our work
- **Economical**, viable both for startups and large enterprises

DIATHEVA HAS OVER 16 YEARS OF EXPERIENCE IN PROVIDING GMP SUPPORT TO THE PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES