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# EuBiologics



Speed up development &  
market launching by specialized  
CRMO Service

# For Health that lasts a life time

We will do our best to make a better world as a biopharmaceutical company supplying a wide range of CRMO services for biopharmaceuticals and manufacturing safe and effective vaccines with the goal of improving global public health.

## **As a customized CRMO service provider, EuBiologics offers specialized services for clients to strengthen their competitiveness.**

EuBiologics is a biopharmaceutical company supplying a wide range of \*CRMO services for biopharmaceuticals. It was incorporated with the objective of being an ideal strategic partner providing proper solutions to clients on development and manufacturing of product. Its facilities are designed to manufacture a variety of mammalian cell and microbial derived protein-based therapeutics and antibodies. It provides customized services in accordance with clients' project stages including cell line development, GMP production, validation and regulatory support.

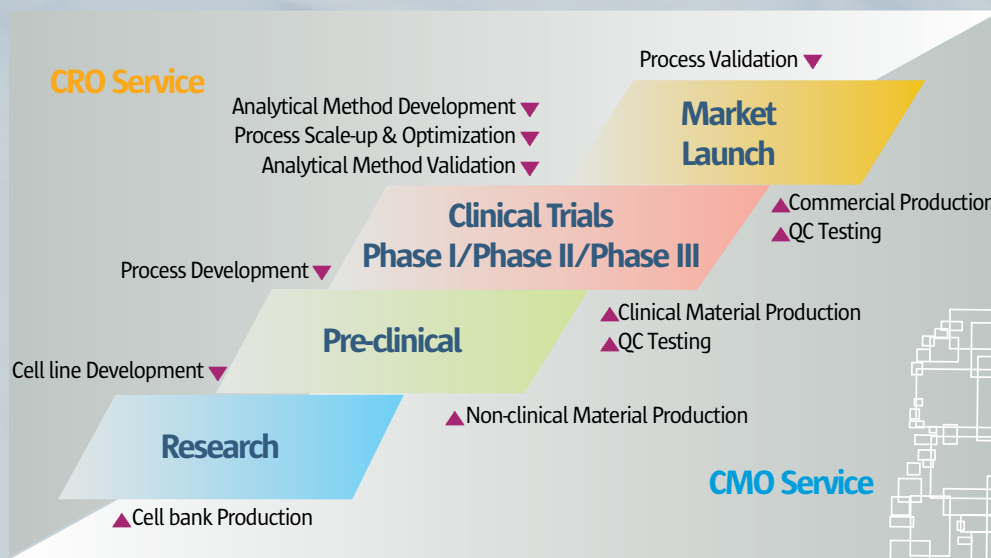
Among keen competition in recent biopharmaceutical market, to achieve the goal in the competition we all have to concentrate what we can do best. As a customized CRMO service supplier, EuBiologics promises to provide clients with specialized tailored services to strengthen their competitiveness.

\*CRMO(Contract R&D and Manufacturing Organization)



## Comprehensive Contract R&D and Manufacturing Service

EuBiologics provides customized services for mammalian cell and microbial derived biopharmaceuticals from cell line development to GMP production. The services are provided in cooperation with global leading companies, aiming at helping clients undertake their projects easily, save their precious time and cost.



EuBiologics's facilities are designed and qualified to meet the latest GMP regulations and guidelines, as well as strictly managed to maintain the optimum conditions maximizing the production efficiency and product safety.





## Contract R&D Service

EuBiologics's R&D services focus on helping clients undertaking their projects easily to save their precious time and cost. The services, aiming at improvement of product quality, optimization of production processes and consulting on the development process are provided.

### Cell Line Development

- **Vector Construction**
  - Gene characterization
- **Cell line Development**
  - Cloning & Selection
  - Optimization
- **Cell line Characterization**
  - Confirmation of identity, homogeneity, purity, suitability and stability

### Process Development

- **Process Development & Scale-up**
  - Media optimization
  - Process development
  - Scale-up & Optimization
  - Process design
- **Technology Transfer**
  - Gap analysis
  - Feasibility assessment
  - Process design

### Formulation Development

- **Formulation Study**
  - Pre-formulation study
  - Formulation study
  - Comparative stability study
- **Lyophilization-cycle Study**

### Analytical Method Development

- **Analytical Method Development**
  - Protein characterization
  - Analytical method
- **Analytical Method Validation**

### Licensing Consulting Service

- **GMP audit**
- **Supporting drug registration with MFDS(Korea), EMA(Europe) and FDA(US)**

※ Some services are provided in cooperation with global leading companies.



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## Contract Manufacturing Service

EuBiologics's CMO services specialize in manufacturing a wide range of mammalian cell and microbial derived biopharmaceuticals including protein therapeutics and antibodies. From early clinical stages to commercial production, most experienced engineers produce relevant materials in accordance with all stages of clients' project development plan under the latest international regulatory standard.

### Cell Bank Production(MCB/WCB)

- Master Cell Bank Production
- Working Cell Bank Production

### Biopharmaceutical APIs Production

- **Mammalian Cell Culture Line**
  - Cell Culture
    - 10L, 30L, 100L Stainless steel bioreactor train
    - 20L, 50L, 200L, 1000L Disposable bioreactor train
  - Purification
    - 150L Ultra-filtration skids
    - Chromatography systems
- **Microbial Fermentation Line**
  - Fermentation
    - 100L, 600L Microbial fermentor train
  - Purification
    - 100L, 600L Ultra-filtration skids
    - Chromatography systems

※For mass production exceeding the capacity, EuBiologics has established collaboration system with global leading companies.

### Finished Product Production

- **Aseptic Glass Vial Filling**
  - 3mL, 5mL, 10mL Vial
  - Max. 2,400vials/hr.
- **Aseptic Plastic Tube Filling**
  - Max. 1.5mL Filling
  - Max. 20,000strips/hr.
- **Lyophilization**
  - Ice capacity: Max. 40kg/cycle





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## Contract QC Testing Service

- **Lot Release Test**
  - Drug substance, Drug product
  - Chemical test, Microbial test, Biochemical test, Bioassay
- **Stability Test**
  - Long-term stability test
  - Accelerated stability test
- **Raw-material Test**



EuBiologics's staff are well trained experts having extensive experiences in development and manufacturing of biopharmaceuticals and inspections of international regulatory authorities.

Even if a problem arises in the midst of clients' project, our professionals will provide support in finding solutions.



## Vision

Speed up development and market launching by specialized service based on extensive experience and advanced technologies

Experts group of abundant experience

Improvement of product quality  
Speed up development and market launching  
Cost saving & risk reduction

GMP Facilities in compliance with the latest international standards

Technical cooperation with the global leading companies

