



## *Contract Manufacturing of Biopharmaceuticals*

From gene to finished vial — **Biovian** is your one-stop-shop providing full range services in cGMP contract manufacturing of biologicals.

Sakari Heyno  
Managing Director  
+358 40 509 3210  
sakari.heyno@biovian.com

Pirkko Kortteinen  
Director, Development and Manufacturing  
+358 40 861 6796  
pirkko.kortteinen@biovian.com

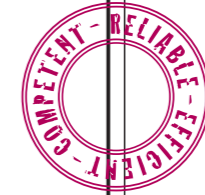
Knut Ringbom  
Director, Projects and Marketing  
+358 40 517 1217  
knut.ringbom@biovian.com



**Competent** - Our experience and know-how in successful development, production and QP release of biopharmaceutical drug substances and drug products, will assure that your project is in good hands

**Reliable** - We live up to our commitments both in terms of quality and timelines. A dedicated project team and project manager will provide an open channel for the customer assuring easy communication throughout all project phases

**Efficient** - Our highly skilled teams combined with state-of-the-art equipment enables flexible and efficient pilot production and process development services



Biovian specializes in process development, scale-up and cGMP contract manufacturing of biopharmaceuticals.

We provide full range service from antigen isolation, expression construct and cell line development, process development, cell cultivation, protein purification to product fill and finish.

Biovian is a privately-owned, independent company. Biovian is a pure service provider, where the customer's project is in focus.



WE OFFER

**cGMP Contract Manufacturing Services**

- Fermentation and cell culture
- Viral vector production
- Protein purification
- Formulation
- Aseptic fill & finish
- Lyophilization
- Analytical Quality Control Services (Ph.Eur. and USP)
- Stability studies according to ICH guidelines
- Cell banking and storage

**Contract Development Services**

- Cell line development
- Process development
- Analytical development
- Proteins for research purposes
- Diagnostic reagents (E.g. antigens and mAb«s)

**Quality Control Services**

Biovian offers also quality control services for drug substances and drug product release. Biovian QC-laboratory complies with the Ph.Eur. and USP as required.

OUR TECHNOLOGIES

**Expression Construct and Cell Line Development**

- Vector cloning, transfections
- Gene amplification
- Clone selection
- Medium optimization

**Hosts**

- Bacteria
- Mammalian cells
- Insect cells
- Yeast

**Fermentation and Cell Cultivation**

- Stirred-tank bioreactors (size: 300 L, 50 L, 35 L)
- Disposable suspension cultivation systems (size: 200 L, 50 L, 10 L)
- Hollow-fiber reactors for both bench-scale and large-scale antibody production with emphasis on diagnostic use

**Protein Purification**

- Varieties of chromatographic methods
- Membrane processes
- Virus clearance development and validation
- DNA and host cell removal and validation

**Formulation and Stability**

- Formulation development for biopharmaceuticals
- Stability studies
- End products and intermediates
- Intermediate and final formulation

OUR TECHNOLOGIES

**Analytical Methods and QC-analyses**

- Immunoassays
- HPLC
- SDS-PAGE
- Western blotting
- IEF
- Peptide mapping
- Total protein
- Host cell protein
- Residual DNA
- Endotoxin
- Sterility
- TOC
- Bioburden
- Mycoplasma
- Microbial challenge tests
- Cell-based assays

**Fill and Finish**

- Aseptic filling
- Lyophilization

FACILITIES

Biovian is located in Finland, in the heart of Turku Science Park with excellent international connections through both Turku and Helsinki international airports.

Biovian's 1 600 m<sup>2</sup> GMP facilities contain EU grade A, B, C and D class clean rooms and warehouse under full quality control as well as extensively equipped development laboratories. Biovian has BSL1 and BSL2 laboratories and is capable to handle micro-organisms classified to GMM1 and GMM2. The main utilities are USP and Ph.Eur grade WFI (Water for Injection) system, pure steam, CO<sub>2</sub>, N<sub>2</sub> and O<sub>2</sub>.