

*From gene to finished vial*

**BIOVIAN**

*Contract Manufacturing of Biopharmaceuticals*

**Biovia**n is a one-stop-shop in GMP contract manufacturing of biopharmaceuticals covering services from early development to finished vial.



Biovia's 2300 m<sup>2</sup> facilities are EMA and FDA certified for GMP production of investigational and commercial medicinal products.

We provide full range service from expression construct

and cell line development, process development, cell cultivation, protein purification to product fill and finish.

Biovia is a privately-owned, financially stable and independent company founded in 2003. Biovia is a pure service provider, where the customer's project is in focus.

Biovia's **Facilities** are located in Finland, in Turku Science Park with excellent connections through both Turku and Helsinki international airports.

Biovia's 2300m<sup>2</sup> GMP facilities contain EU grade A, B, C and D class cleanrooms and warehouse under full quality and 24/7 facility

monitoring control.

The manufacturing operations are supported by extensively equipped development laboratories. Biovia facility



has BSL1 and BSL2 approval with an option to BSL3 extension if required by the client. The main utilities are USP and Ph.Eur grade WFI (Water for Injection) system, isolator, pure steam, CO<sub>2</sub>, N<sub>2</sub> and O<sub>2</sub>,

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

**Competent**

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 and exact communication throughout all project phases.

**Reliable**

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

**Efficient**

## *GMP Contract Manufacturing Services*

### **Microbial and Yeast production**

- Fermentation capacity 20–200 L
- Fermentation of wide range of micro-organisms (E.coli, Yeast etc.)

### **Mammalian production**

- Cell cultivation capacity 5–500 L

### **Insect cell production**

- Cell cultivation capacity 1–100 L

### **Viral vector production**

- Dedicated production facility for viral vector production
- Production in disposable bioreactors (suspension, adherent, microcarriers)
- Purification by chromatographic methods or by ultracentrifugation
- Formulation and final Purified Bulk manufacture

### **MCB and WCB manufacture and storage**

- Dedicated facilities for microbial, mammalian, yeast and insect GMP cell banking
- Long or short-term GMP storage of cell banks

### **MVSS and WVSS manufacture and storage**

- Dedicated facilities for master and working virus seed stock manufacture (adenovirus, baculovirus, lentivirus etc.)
- Long or short-term GMP storage of seed stocks

### **Protein purification**

- Extensive harvesting and clarification equipment
- Cell disruption
- Comprehensive protein purification solutions
- Virus removal and inactivation steps as applicable
- Formulation and final Drug Substance bulk manufacture



### **Aseptic Fill & Finish**

- Formulation and final Drug Product manufacture
- Two automated filling lines, filling in vials
- Batch sizes 200–7000 vials
- Lyophilisation

### **Stability studies according to ICH guidelines**

- Controlled cabinets for stability studies
- Study planning, testing and reporting

### **Drug Product labelling, packaging, storage and QP release**

## *Quality Control Services*

Biovia offers quality control services for Drug Substances and Drug Product release. Biovia QC-laboratory complies with Ph.Eur. and USP.

- Comprehensive analytical methods supporting DS and DP production and batch release
- Product specific assays
- Cell based assays
- Microbiological QC and safety assays (Sterility, Bioburden, Endotoxin etc.)

## *Contract Development Services*

- Cell line Development
- Process Development
- Analytical Development

# BIOVIAN

Biovia Ltd  
Tykistökatu 6 B  
FI-20520 Turku, Finland  
email: [contact@biovian.com](mailto:contact@biovian.com)  
[www.biovian.com](http://www.biovian.com)

## Contact information

**Dr. Knut Ringbom**  
CEO

+358 40 517 1217  
[knut.ringbom@biovian.com](mailto:knut.ringbom@biovian.com)

**Mr. Antti Nieminen**  
Director,  
Business Development and Projects  
+358 40 502 1332  
[antti.nieminen@biovian.com](mailto:antti.nieminen@biovian.com)

**Dr. Pirkko Kortteinen**  
Director,  
Development and Manufacturing  
+358 40 861 6796  
[pirkko.kortteinen@biovian.com](mailto:pirkko.kortteinen@biovian.com)