From gene to finished vial

BIOVIAN

Contract Manufacturing of Biopharmaceuticals

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

Biovian's 2300 m^2 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.

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

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

Biovian's 2300m^2 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. Biovian 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_2, N_2 and O_2.

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 bio-reactors (suspension, adherent, microcarriers)
- Purification by chromatographic methods or by ultracentrifuga-tion
- Formulation and final Purified Bulk manufacture

MCB and WCB manufacture and storage
- Dedicated facilities for micro-bial, mammalian, yeast and insect GMP cell banking
- Long or short-term GMP storage of cell banks

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

Biovian offers quality control ser-vices for Drug Substances and Drug Product release. Biovian 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.)

MVSS and WVSS manufacture and storage
- Dedicated facilities for master and working virus seed stock manufacture (adenovirus, bacolovirus, 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

Contract Development Services

- Cell line Development
- Process Development
- Analytical Development

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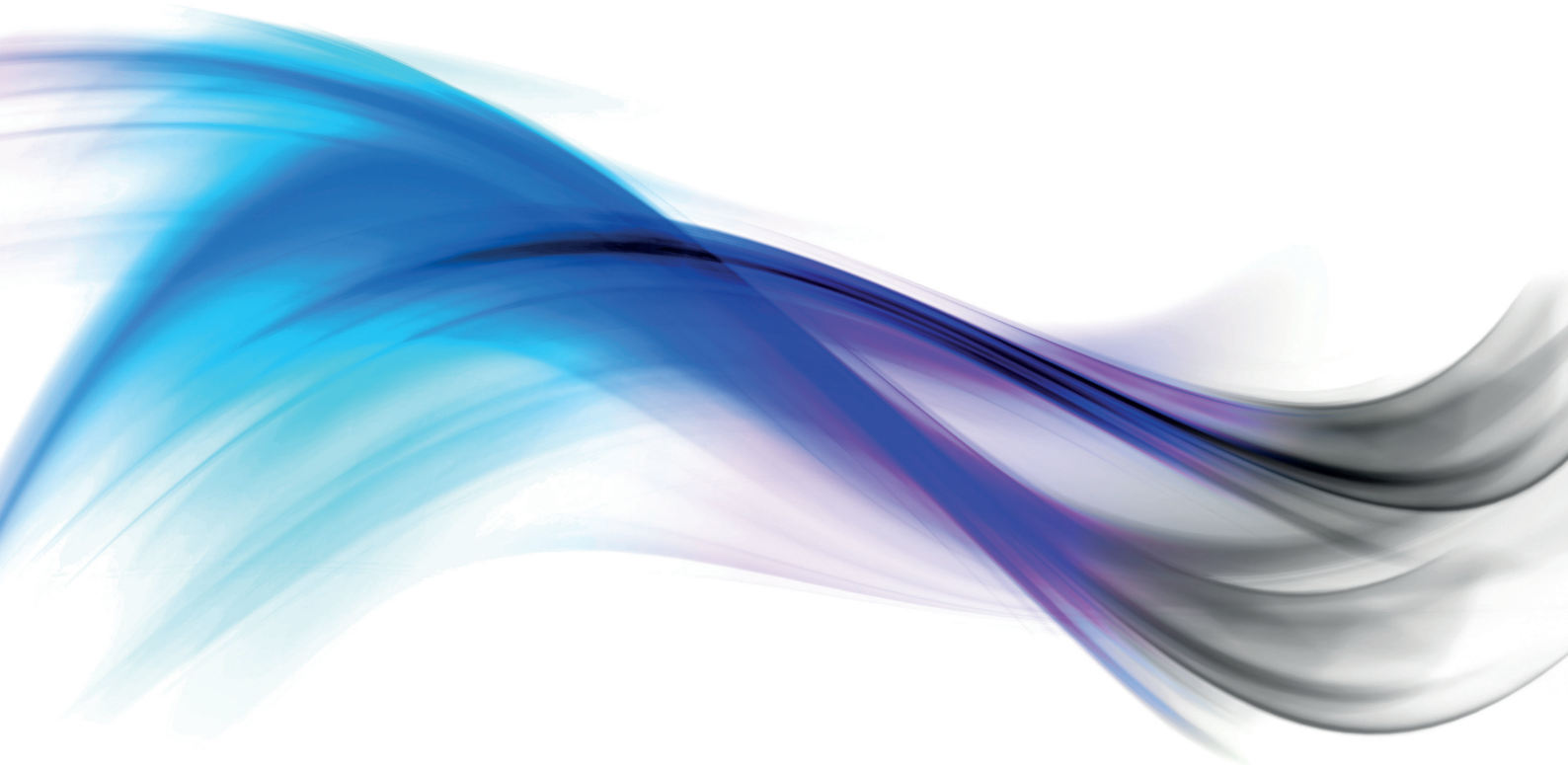

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