From gene to finished vial –
from the laboratory bench to the clinic

BIOVIAN

Contract Development and
Manufacturing of Biopharmaceuticals

BIOVIAN
PREMIUM BIO-CDMO
FROM THE TOP OF THE WORLD

ABOUT US

Biovian is a Nordic Bio-CDMO that provides premium GMP services to biotech companies developing innovative gene therapies or biopharmaceuticals. Our primary goal is to turn the client's innovation into a manufacturable product by taking projects from the laboratory bench to the clinic. To do so we offer our clients a true One-Stop-Shop GMP CDMO service, with modularity available from gene to finished vial. We specialize in contract development and manufacturing of Viral Vectors for gene therapy as well as GMP plasmid DNA and recombinant protein-based biopharmaceuticals using microbial production hosts.

FACILITIES

The facilities of Biovian, encompassing 4600 m^2, are located in Turku Science Park in Turku, Finland, with excellent connections through both the Turku and Helsinki international airports. The facilities and processes are EMA certified and FDA inspected for GMP production of both investigational and commercial medicinal products. We are continuously expanding our production facilities to enable us to support versatile cutting-edge biopharmaceutical manufacturing needs.

WORKING WITH US

For us at Biovian people are always in focus. We foster and encourage an open dialogue, and we value a partnership with our clients. It is extremely important that our client can feel completely safe and have trust in Biovian, when it comes to keeping information confidential and providing agreed deliverables. We operate according to mutually set targets and provide our clients with the agreed products on time and within budget.

WE ARE MORE THAN A CDMO - WE CARE

"We do what we say we will do". This expression encapsulates the way Biovian has served a global client base for well over a decade. Our straight-forward way of approaching tasks originates from the Nordic ethos, where being as good as one's word is a value of highest priority. We believe that personal contacts, friendliness and reliability are essential in customer relationships.

Our comprehensive understanding of the design of manufacturing processes helps you avoid delays and additional costs associated with last-minute changes in production technologies.

BIOVIAN IS A TRUE ONE-STOP-SHOP GMP CDMO

Biovian offers clients a true One-Stop-Shop GMP CDMO service, with modularity available across both the supply chain and the value chain. In the supply chain the services of Biovian span from master cell and virus banking to Qualified Person-approved release of the final labelled Drug Product. Similarly, in the value chain the services of Biovian run from preclinical supply up to commercial supply or manufacturing, enabling us to continue supporting you as you take molecules through development and onto the market. At each stage, Biovian adheres to GMP and operates out of fully inspected and fully certified facilities.

WHAT ARE THE BENEFITS OF A TRUE ONE-STOP-SHOP?

When partnering with us there is no need to use several service providers, which can be both time-consuming and expensive. The One-Stop-Shop CDMO concept of Biovian is designed to keep the drug development project on a cost-effective and regulation-compliant path during clinical development and manufacturing.

COMPREHENSIVE SERVICES FOR THE PHARMACEUTICAL INDUSTRY

QUALITY CONTROL SERVICES

Biovian provides comprehensive analytical and microbiological quality control services to support Drug Substance and Drug Product development projects. Our testing laboratory also provides QC services separate from CDMO programs, e.g. compendial analyses (European Pharmacopoeia, Ph. Eur., and USP Standards) as well as microbiological analyses of medicinal products, medical devices, raw materials and packaging.

Examples of QC analyses:

- Identity, potency, safety and purity analyses
- Compendial analyses, Ph. Eur. and USP
- Microbiological QC and safety analyses, Ph. Eur. and USP (e.g. sterility testing, bioburden, endotoxin testing)

Stability studies:

- Accelerated stability studies
- Storage conditions according to ICH guidelines -70°C / -20°C / +5°C / +25°C

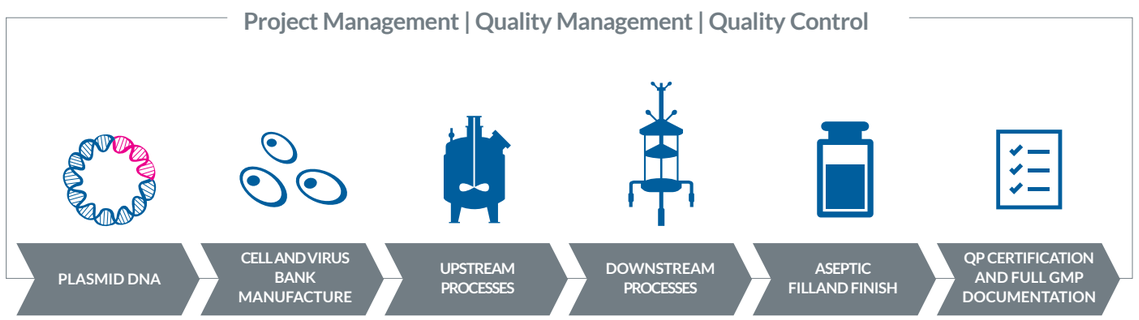
QUALITY MANAGEMENT

Biovian has an experienced Quality Management team that reviews every aspect of the manufacturing, from raw materials to final shipping, and makes sure that Good Manufacturing Practice is followed. We also have our own team of Qualified Persons (QPs) who certify each batch for release.

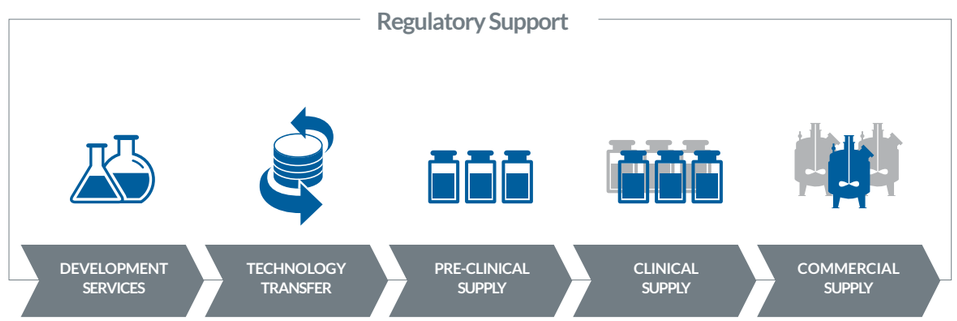
Our QM and QP services include the following:

- GMP advice during biopharmaceutical product development and production
- Regulatory support for biological Drug Substances and Drug Products
- Full GMP documentation, including GMP certificates
- Detailed batch records
- QA approval of the release for GMP Cell Banks and Viral Seed Stocks
- QP certification of each batch (Drug Substances, Drug Products, IMPs)

ONE-STOP-SHOP SERVICES ACROSS THE SUPPLY AND THE VALUE CHAIN



SUPPLY CHAIN - FROM GENE TO FINISHED VIAL



VALUE CHAIN - FROM THE LABORATORY BENCH TO THE CLINIC

"We can make your CMC journey easier."

BIOVIAN – ONE-STOP-SHOP BIO-CDMO SERVICES

VIRAL VECTOR PRODUCTION

Biovian holds an EMA license for manufacturing of Viral Vector products for clinical trials as well as for commercial use. We offer GMP-grade produc- tion of AAV and adenovirus, and have the readi- ness to produce other biosafety level 2 (BSL2) class viruses.

Adenovirus
AAV
Other biosafety level 2 (BSL2) class viruses

- Suspension Cell Culture in single-use bioreactors – up to 200 L
- Adherent Cell Culture in multilayer flasks, packed-bed bioreactors or single-use bioreactors based on microcarriers
- Ultracentrifugation or chromatography-based Downstream Processes
- Comprehensive purification solutions

PLASMID DNA PRODUCTION

Biovian manufactures plasmid DNA for a variety of client projects. One of our main focus areas is Viral Vector manufacturing for those gene therapies, where plasmid-DNA constructs serve as key raw material. Our GMP plasmid DNA may also be used to develop novel DNA or mRNA Vaccines and non-viral Gene Therapy applications.

GMP plasmid DNA

- Fermentation options up to 200 L
- Chromatographic purification
- Tangential flow filtration
- Etc.

MICROBIAL PRODUCTION

Biovian provides bacterial and yeast-based production of Drug Substances and Drug Products. We provide fermentation of a wide range of aerobic and anaerobic microbes. Manufacturing and purification options cover both secreted and intracellular products.

Recombinant proteins

- Capacity for up to 200 L in Stainless Steel Stirred Tanks
- Tangential Flow Filtration units and centrifugation for harvest clarification and further processing
- Homogenization
- Comprehensive purification methods – refolding, chromatography, membrane processes, Tangential Flow Filtration

CELL BANK AND VIRUS SEED STOCK

Biovian provides both the preparation and the storage of Cell Banks and Virus Seed Stocks in accordance with current regulatory guidelines.

Research Cell Bank (RCB)
Master Cell Bank (MCB) Working Cell Bank (WCB)

Research Virus Seed Stock (RVSS) Master Virus Seed Stock (MVSS) Working Virus Seed Stock (WVSS)

- Dedicated clean rooms
- GMP-compliant storage
- 24/7 monitoring of facilities
- Flexible shipment to other sites
- Etc.

FILL AND FINISH

Aseptic Fill and Finish is a core competence of Biovian, with an expertise with continuous operation for over a decade. Aseptically filled GMP-certified Drug Products can be used for clinical trials or for commercial purposes.

Viral Vectors
Plasmid DNA
Recombinant proteins Dilution buffers Placebos

- Dedicated filling lines for BSL1 and BSL2 products
- Range of volumes: from 0,5 mL to 100 mL
- Vial-sizes 2R and 10R validated (ask for custom options)
- Batch size ranges from 50 to 10 000 vials
- BSL1 up to 10 000 vials
- BSL2 up to 1000 vials
- Inhouse release testing including sterility testing and 100% visual inspection

PROCESS DEVELOPMENT

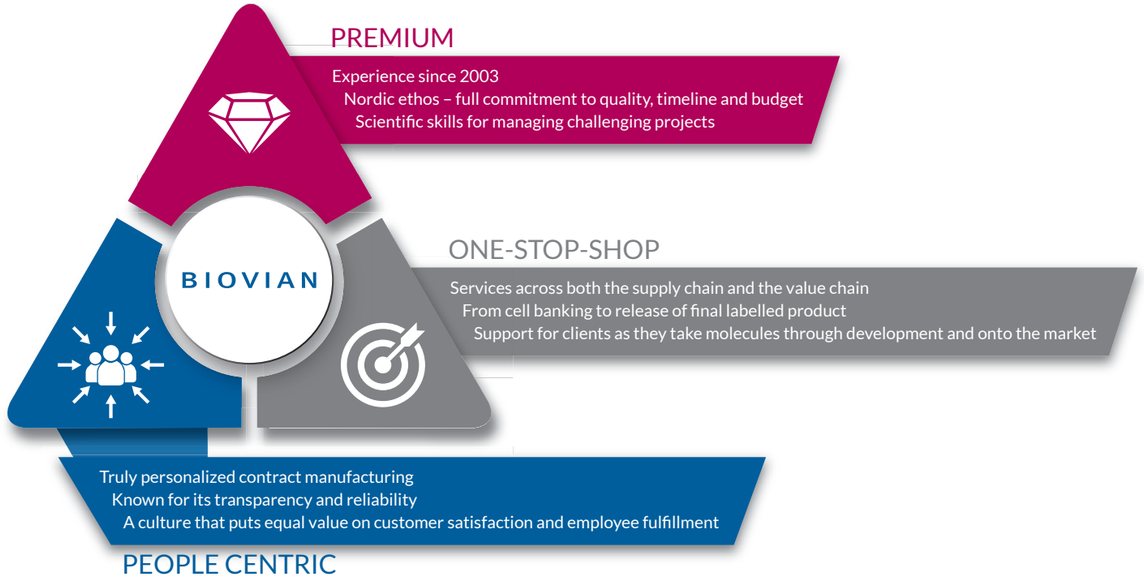
Biovian provides comprehensive process development services that are fully integrated with process analytics. Our process development services support Quality By Design (QBD) approach from the earliest possible stage to enable a straightforward transition to GMP production.

Process development and validation
Analytical development and validation

- Upstream process development e.g. optimization of cell culture and fermentation conditions
- Downstream process development e.g. chromatographic purification and filtration technologies

BIOVIAN - YOUR PARTNER IN GMP CONTRACT DEVELOPMENT AND MANUFACTURING OF BIOPHARMACEUTICALS

Biovian is removing bottlenecks with its complete One-Stop-Shop service. Guided by the Nordic ethos, Biovian has built a reputation for delivering high-quality work on time and on budget to a global client base. Biovian is continu- ing to expand its operation, adding scale and capabilities to support the development of breakthrough therapies.



"We are a true One-Stop-Shop."

BIOVIAN

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