Your One-Stop-Shop for Viral Vector production

BIOVIAN

Contract Development and Manufacturing of Biopharmaceuticals
**BIOVIAN** is your One-Stop-Shop in GMP contract development and manufacturing of Viral Vectors. We have established our position as an experienced, global GMP producer of Viral Vectors for gene therapy applications, immunology and vaccines. Biovian holds an EMA license for manufacturing of Viral Vector products for clinical trials as well as for commercial use.

“An expert CDMO partner can provide guidance on the ATMP procedure, as well as on producing or sourcing of specific GMP-grade components, reagents and consumables needed for Viral Vector production.”

*Knut Ringbom, CEO*

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**VIRAL VECTOR CDMO EXCELLENCE WITH IN-HOUSE PLASMID PRODUCTION**

Adenovirus vectors
Adeno Associated Virus vectors, AAVs
Other biosafety level 2 (BSL2) class viruses.
Plasmids

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**ONE-STOP-SHOP SERVICES FOR VIRAL VECTOR PRODUCTION**

**CELL BANKS AND VIRUS SEED STOCK**
- Research Cell Bank (RCB)
- Master Cell Bank and Working Cell Bank (MCB/WCB)
- Master Viral Seed Stock and Working Viral Seed Stock (MVSS/WVSS)

**UPSTREAM PROCESSES**
- Suspension Cell Culture in single-use bioreactors – up to 200 L
- Adherent Cell Culture in multilayer flasks, packed-bed bioreactor and single-use bioreactors with microcarriers

**DOWNSTREAM PROCESSES**
- Ultracentrifugation-based processes
- Chromatography-based processes
- Comprehensive purification solutions – chromatography, membrane processes, Tangential Flow Filtration processes (TFF)

**ASEPTIC FILL AND FINISH**
- Formulation and final Drug Product manufacture
- Automated Aseptic Filling line for live Viral Vectors – Filling into vials
  - Batch sizes 200–1000 vials

**QUALITY ASSURANCE AND QUALITY CONTROL**
- Product specific assays
- Impurity analysis
- Cell based assays
- Microbiological QC and safety assays (sterility, bioburden, endotoxin etc.)
- QP Certification and full GMP documentation

**FINISHED PRODUCT, READY FOR USE IN CLINICAL TRIALS**

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**VIRAL VECTOR CDMO FACILITIES**

The Viral Vector production facility of Biovian allows for flexible contract development and GMP production scenarios. The state-of-the-art, biosafety level 2, production facility includes:

- 200 L scale single-use bioreactor
- Chromatographic purification
- Tangential Flow Filtration (TFF) processes
- Full analytical support
- Full support for process development

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**PROCESS DEVELOPMENT SERVICES**

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

- Upstream Process development
- Downstream Process development
- Analytical development
- Development and set-up of in-process control
- Formulation development
VIRAL VECTOR QA DOCUMENTATION PACKAGE

The documentation packages for Viral Vector projects include e.g. the following:

- TSE/BSE certificate
- Certificate of Analysis
- Certificate of GMP compliance
- Comprehensive batch-manufacturing record
- CMC package for IMPD/IND

“The regulatory documentation of Biovian is excellent.”
- Client, Adenovirus vector project

From gene to finished vial – from the laboratory bench to the clinic
EXPLORE OUR VIRAL VECTOR SERVICES

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