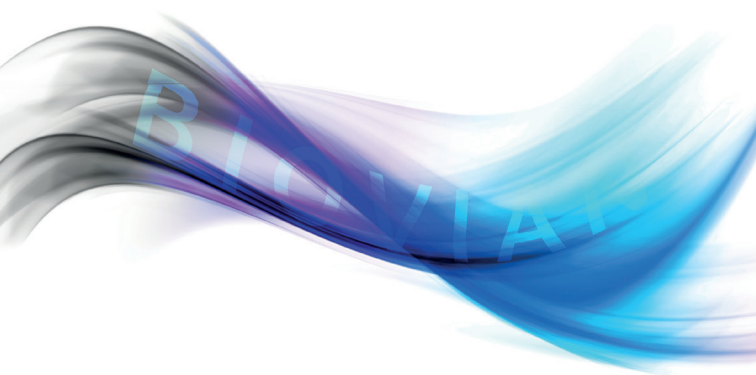


*Your One-Stop-Shop for
Viral Vector production*



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.



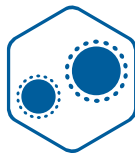
"An expert CDMO partner can provide guidance on the ATMP procedure, as well as on producing or sourcing of specific GMP-grade components, reagents and consumables needed for Viral Vector production."

-Knut Ringbom, CEO

VIRAL VECTOR CDMO EXCELLENCE WITH IN-HOUSE PLASMID PRODUCTION

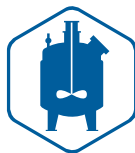
Adenovirus vectors
Adeno Associated Virus vectors, AAVs
Other biosafety level 2 (BSL2) class viruses.
Plasmids

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**

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



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

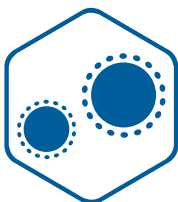
Certificate of GMP compliance

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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