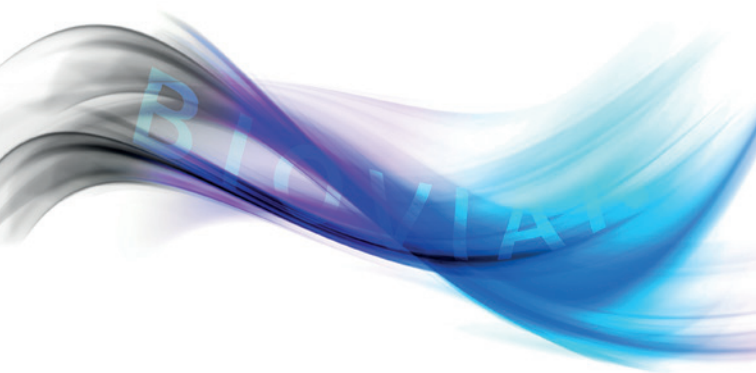


*Your One-Stop-Shop for
GMP plasmid DNA production*



BIOVIAN

*Contract Development and
Manufacturing of Biopharmaceuticals*

BIOVIAN offers premium plasmid DNA CDMO services for preclinical, clinical and commercial production. In our Plasmid DNA production we adhere to the same GMP standards whether it is a starting material or a final drug product.



"When partnering with us there is no need to use several service providers, which can be both time-consuming and expensive."

-Knut Ringbom, CEO

GMP-GRADE PLASMID DNA

The benefit of choosing a GMP-grade, yet cost-effective, plasmid CDMO from the start, lies in the smooth regulatory transition to the next steps. Our platform approach to plasmid DNA production where plasmid constructs can efficiently be produced using readily defined processes, minimizes the time needed from project set-up up to Drug Substance or Drug Product delivery.

PLASMID DNA APPLICATIONS

Viral Vector production (e.g. AAV, Lentivirus)
 Cell and gene therapy
 DNA Vaccines
 mRNA production

PLASMID DNA PRODUCTION

We have the flexibility to deal with Plasmid DNA projects of various sizes. The options for E. coli fermentation for GMP plasmid DNA production extend up to 200 L.

ONE-STOP-SHOP SERVICES FOR GMP PLASMID DNA



CELL BANKS

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



UPSTREAM PROCESSES

Plasmid production in the selected E. coli strain
 Fermentation options up to 200 L
 Harvesting by centrifugation / Tangential Flow Filtration
 Cell lysis



DOWNSTREAM PROCESSES

Chromatographic purification
 Formulation by Tangential Flow Filtration



ASEPTIC FILL AND FINISH

Formulation
 Fill and Finish



QUALITY ASSURANCE AND QUALITY CONTROL

QC release testing
 QP Certification and full GMP documentation

DRUG PRODUCT OR STARTING MATERIAL FOR
 VIRAL VECTOR MANUFACTURING

WE ARE MORE THAN A CDMO – WE CARE

For us at Biovian people are always in focus. We foster and encourage an open dialogue and value a partnership with our clients. We operate according to mutually set targets and provide our clients with the agreed products on time and within budget.



QUALITY CONTROL TEST PACKAGE

Quality control packages will be provided according to your product specific requirements.

THE QC TESTS INCLUDE E.G. THE FOLLOWING

Appearance
 pH
 DNA concentration and purity
 Total Plasmid purity
 Identity
 Supercoiled DNA purity
 Residual host cell protein, DNA and RNA
 Residual reagents
 Bioburden and sterility
 Endotoxin
 Sequence

PLASMID QA DOCUMENTATION PACKAGE

Biovian has an excellent track record in supporting clients with regulatory-compliant documentation.

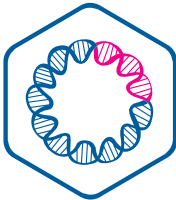
THE DOCUMENTATION PACKAGES FOR PLASMID DNA PROJECTS INCLUDE E.G. THE FOLLOWING

TSE/BSE certificate

Certificate of Analysis

Certificate of GMP compliance

Comprehensive batch-manufacturing record



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

EXPLORE OUR PLASMID DNA SERVICES



FOLLOW US ON



CONTACT



contact@biovian.com



Tykistökatu 6 A, Biocity
FI-20520 Turku, Finland



www.biovian.com