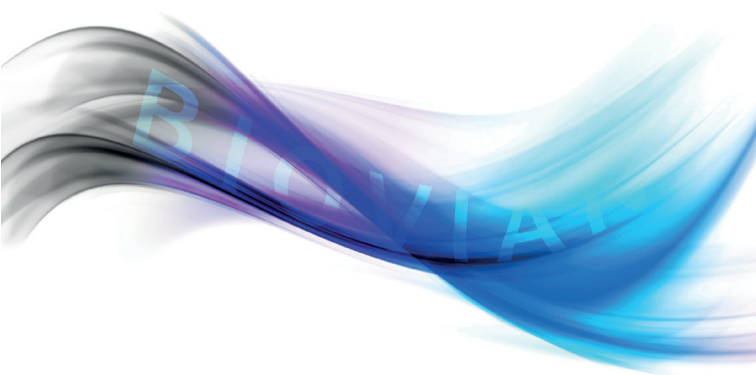


*Your One-Stop-Shop for  
Microbial Production*



**BIOVIAN**

*Contract Development and  
Manufacturing of Biopharmaceuticals*

**BIOVIAN** is a One-Stop-Shop CDMO for bacterial and yeast-based production of Drug Substances and Drug Products. Our services include GMP production of first-in-class biopharmaceuticals such as recombinant proteins and plasmid DNA. Manufacturing and purification options cover both secreted and intracellular products.



*"My experience with Biovian is based on a long-term project that includes both Drug Substances and Drug Products. Biovian has been a good partner. The project, comprising development and several technical and GMP batches, was on time and within budget over a period of 5-6 years – I believe that could be a world record!"*

-CEO, consultant

## EXAMPLES OF CAPABILITIES IN MICROBIAL PRODUCTION

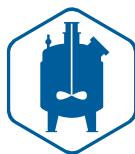
Recombinant proteins and protein complexes  
GMP Plasmid DNA  
Vaccines

## ONE-STOP-SHOP SERVICES FOR MICROBIAL PRODUCTION



### CELL BANKS

Research Cell Banks  
Master Cell Banks and Working Cell Banks



### UPSTREAM PROCESSES

Stirred tank bioreactors – up to 200 L  
Fermentation of aerobic and anaerobic bacteria and yeasts  
Tangential flow filtration or continuous centrifugation for harvest clarification  
Cell homogenization



### DOWNSTREAM PROCESSES

Refolding  
Chromatographic purification  
Membrane purification  
Tangential Flow Filtration



### ASEPTIC FILL AND FINISH

Formulation and final Drug Product manufacturing  
Automated aseptic filling lines with RABS  
Filling of vials – 2R and 10R  
Up to 10 000 vials per batch  
Labelling



### 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 CLINICAL TRIALS

## CDMO EXPERIENCE SINCE 2003

Biovian has developed microbial production processes since 2003 and manufactured GMP batches for clinical studies. The microbial GMP-manufacturing unit of Biovian is equipped with state-of-the-art fermenters, harvesting equipment and a choice of downstream purification capabilities.



## ANALYTICAL SERVICES

Analytical testing and analytical method development are a central part of Biovian expert services. Quality control tests, such as tests for sterility, bioburden and endotoxin, are routinely performed in-house. Product specific QC tests are developed and validated, as Biovian has a team with profound knowledge of pharmaceutical method development and validation.

### EXAMPLES OF SPECIFICATION ANALYSES

Appearance  
pH  
Osmolality  
Identity, Concentration, Potency, Purity  
Sterility  
Visible and subvisible particles  
Residual reagents

## QA DOCUMENTATION PACKAGE

THE DOCUMENTATION PACKAGES FOR MICROBIAL PROJECTS INCLUDE E.G. THE FOLLOWING

TSE/BSE certificate

Certificate of Analysis (CoA)

Batch certificate

Certificate of GMP compliance

GMP production summary report

### CMC DOCUMENTATION

IND/IMPD CMC documentation support



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

EXPLORE OUR  
MICROBIAL PRODUCTION SERVICES



FOLLOW US ON



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