



## CMC Testing Support for Gene and Cell Therapy

The development of Advanced Therapy Medicinal Products (ATMPs), such as gene and cell therapy products, has made significant progress in the treatment of many diseases, including cancer, genetic, and autoimmune disorders.

With the promise to enhance treatment, greatly reduce side effects, and potentially cure many types of diseases and disorders, these therapies are in high demand, and biopharma companies are in a race to the clinic. However, these technologies are very complex in nature and are vastly different than traditional biopharmaceutical products, especially when it comes to the use of these products for personalized medicine. The complexities span the development pipeline, creating challenges for manufacturing, testing requirements, regulatory approval, and commercialization.

Eurofins BioPharma Product Testing supports the development of ATMPs both for traditional use as well as for use in personalized medicine. We provide comprehensive GMP-compliant CMC testing support to ensure the identity, potency, purity, and safety of starting materials, intermediate products, vectors, and final drug products as well as support for manufacturing process development and validation.

### Why Choose Eurofins BioPharma Product Testing?

- We offer comprehensive cell and molecular biology, biochemistry, biosafety, and microbiology testing through one testing partner.
- We have provided cGMP-compliant testing support to gene and cell therapy sponsors for over 10 years and also support most contract manufacturers focused on ATMPs.
- We have vast experience in supporting cell and gene therapy manufacturing from early clinical, through process validation, product optimization, and marketed release.
- We have the laboratory capacity, BSL2 facilities, and state-of-the-art instrumentation to meet regulatory requirements and turnaround times for cell and gene therapy products.



- Our specialized sample delivery and receipt process ensures seamless communication between our lab and yours and expedites your samples into our laboratory.
- Our secure 24/7 online data portal, LabAccess.com, provides timely access to your test results, as well as the associated raw data for each test method.
- Our experienced project management and technical teams serve as your single-source solution for all of your testing needs.

### Therapies Supported

- Gene Therapies – Viral Vector, Nanoparticle Vector, Plasmid Based, iRNA/mRNA
- Cell Therapies – Autologous, Allogeneic, Xenogeneic
- Oncolytic Viral Therapies

### Comprehensive Cell and Gene Therapy Testing Capabilities

#### Raw Materials

Eurofins BioPharma Product Testing is well-versed in evaluating critical quality attributes (CQAs) of a diverse range of ancillary and raw materials, including monographed and non-monographed materials, such as chemically defined growth media, process buffers, cytokines, growth factors, and enzymes using platform GMP methods as well as customized methods developed to fit unique client needs.

Our 20 years of biopharmaceutical testing experience, dedicated teams of 150 raw materials scientists, and state-of-the-art instrumentation allow us to quickly



establish methods so routine samples can be tested and reported in 8-10 business days.

## Cell Banks

Eurofins BioPharma Product Testing offers expert capabilities for the preparation and characterization of a wide variety of mammalian and insect cell banks. We offer GMP production of master and working cell banks, GMP non-production (reagent or bioassay) master and working cell banks and R&D cell banks as well as banking for end-of-production cells upon request. We perform all GMP production cell banking in our clean rooms, including animal origin free (AOF) suites in accordance with EMA and/or FDA requirements. We also support characterization of cell banks, including sterility, mycoplasma, adventitious and endogenous viruses, and identity testing. Additional tests that may be needed include transgene expression and biochemical and cell-surface marker analysis.

## Virus Banks

Virus banks may be used to produce a viral vector drug substance, to generate helper virus, or for ex vivo generation of cells for therapy. Eurofins BioPharma Product Testing provides extensive services for the characterization of your virus banks to ensure identity, potency, and safety prior to the use of these vectors in production. We support characterization of viral banks, including sterility, mycoplasma, adventitious viruses, identity, infectious and genomic titers, and replication-competent virus testing.

## Plasmids

Multiple plasmids containing various components required for viral packaging and transgene delivery are often utilized for the production of Gene Therapy viral vectors. These plasmids are considered as critical ancillary materials and must go through a rigorous testing program to ensure the efficiency of manufacturing process as well as the safety and potency of the drug substance. Plasmids produced

in bacteria should be tested for sterility and endotoxin as well as properties such as concentration, purity, identity by sequencing, and integrity.

## Harvest (Lot Release Testing)

Eurofins BioPharma Product Testing offers a streamlined cGMP approach to lot release testing. Our experienced team will help you ensure product purity and safety in order to move your product into downstream purification faster and with less risk of contamination.

As part of our Lot Release Testing package, we offer tests, including bioburden, mycoplasma testing (compendial and rapid), in vitro viral screening, and virus specific qPCR assays with test reports within 35 calendar days and interim results upon request. Additional tests include infectious titer or tests for the presence of replication-competent viruses.

## Bulk and Finished Products

To meet the critical quality attributes of identity, potency, purity, safety, and stability it is common for ATMPs to have over 30 methods to test bulk and finished products for release to the clinic or market. Eurofins BioPharma Product Testing offers the most comprehensive cGMP method establishment, characterization, ICH method validation, release and stability testing of any contract testing laboratory. We have developed and validated numerous assays to evaluate products and impurities, such as product and process residuals, in a wide variety of methodologies, including bioassay, ELISA, qPCR, chromatography and MS applications. For most products, we have the ability to establish all methods and execute all tests at one location. We also offer 80,000 cubic feet of stability storage as well as dedicated laboratories and staff for stability and release testing.

### Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing  
Cell Banking Services • Virology Services • Facility & Process Validation  
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology  
Stability Testing & Storage • Primary & Secondary Package Testing

### Flexible Service Models

Fee For Service (FFS)  
Full-Time-Equivalent (FTE)  
Professional Scientific  
Services® (PSS)

### Global Facilities

Australia	Denmark	India	Japan	Spain	UK
Belgium	France	Ireland	Netherlands	Sweden	US
Canada	Germany	Italy	New Zealand	Switzerland	