eurofins | BioPharma Product Testing

Bioassays for Gene Therapy Products

Gene therapy products are a unique class of biopharmaceuticals that offer exciting potential to treat life-threatening or debilitating diseases. Like all biopharmaceuticals, critical quality attributes of gene therapy products need to be carefully assessed to ensure product safety and efficacy. Unlike traditional protein therapeutics, efficacy of gene therapy products depends on multiple coordinated steps, including efficient cell entry, expression of the gene of interest, and proper biological function of the protein. Consequently, a matrix approach involving multiple bioassays - such as an infectivity assay combined with one or more functional assay(s) - are often required to sufficiently characterize the products. Oftentimes, the complexity of the mechanism of action also leads to higher intrinsic variability in bioassays, making them the most challenging assays to implement in quality control.

Eurofins BioPharma Product Testing offers extensive experience in bioassay development, optimization, phase appropriate method validation/transfer, as well as assay maintenance to support routine lot release and stability testing.

Why Choose Eurofins BioPharma Product Testing?

Unmatched expertise and proven track record for cGMP potency assay testing ensures successful and timely completion of your testing program.

We have more experienced Ph.D.s than any other contract laboratory, including scientists dedicated to troubleshooting problematic assays and developing new assay platforms and methodologies.

We offer a phase appropriate validation approach to meet early clinical stage, late clinical stage, and commercialization of your product.

Our secure, 24/7 online data portal, LabAccess.com, provides timely access to your test results.

Product Types

- Plasmid Vector
- Lentiviral Vector
- Helper Dependent Adenoviral Vector
- Adeno Associated Viral Vector (AAV)
- Retroviral Vector
- Oncolytic Viral Therapies
- Viral Like Particles (VLP)

Assay Experience

- Viral vector TCID50 titration assay with qPCR and ddPCR readout
- Vector potency assay - transduction/transfection followed by gene expression and/or functional readout using qPCR/ddPCR, quantitative and binding ELISA, flow cytometry and enzymatic assays.

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)
PSS Insourcing Solutions®

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