eurofins

BioPharma
Product Testing

Gene Therapies

Eurofins BioPharma Product Testing Ireland

ABOUT
EUROFINS BIOPHARMA PRODUCT TESTING IRELAND

Delivering analytical insight, regulatory readiness, and scientific partnership needed to move complex gene therapies efficiently from concept to clinic.

Eurofins BPT Ireland is a GMP-compliant, analytical centre of excellence, supporting gene therapy programs from early development through commercial manufacture.

As part of the global Eurofins network of laboratories, we seamlessly integrate local insight with worldwide scientific and regulatory capabilities. This combination enables customised, science driven solutions that reduce development risk and support global clinical and commercial strategies.

Sponsors partner with Eurofins BPT Ireland for reliable execution, technical depth, and continuity across the product lifecycle.

Gene therapy development demands analytical strategies that anticipate regulatory expectations and withstand the pressures of late stage development and commercial release.

We offers a single site, lifecycle focused model for gene therapy testing, providing continuity from early development through commercial supply. Our teams combine deep modality expertise with EU in country release capability and global regulatory alignment, helping sponsors reduce risk, avoid rework, and progress programs with confidence.

As part of the Eurofins BioPharma Product Testing network of laboratories we provide sponsors with both local accountability and access to global scientific expertise, while maintaining a dedicated focus on advanced and complex biological products.

ACCESS TO THE GLOBAL MARKET

Testing performed at Eurofins BPT Ireland supports EU in country release requirements and global product release.

REGULATORY EXPERTISE

GxP-aligned site, operating under FDA requirements and EU regulatory oversight via HPRA inspection, in line with EMA expectations, and aligned with applicable ICH guidelines and ISO 14001 requirements.

ANALYTICAL SERVICES–ONLY FOCUS

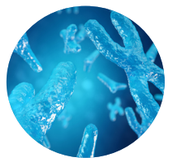
Exclusively dedicated to analytical services, giving deep technical expertise, prioritised testing, and a tailored approach across all phases.

FLEXIBLE SERVICE MODELS

Multiple business models available to suit your needs: Fee for Service (FFS), Full Time Equivalent (FTE), or PSS Insourcing Solutions®.

SINGLE-SITE TESTING, FEWER AUDITS

The majority of gene therapy testing can be performed on one site, reducing audit burden and simplifying vendor management.



END-TO-END GENE THERAPY EXPERIENCE - SCALABILITY WITHOUT DISRUPTION

Extensive experience supporting gene therapy programmes from early method development through to commercial release, across multiple modalities.

GENE THERAPY–SPECIALISED INFRASTRUCTURE

Purpose-built laboratories, equipment, and teams designed specifically for advanced therapies.

Gene therapies are a diverse class of advanced biological medicines that use genetic material to address disease at its source. Their complexity and sensitivity require specialised analytical strategies

Gene therapies encompass a broad range of therapeutic strategies, including gene replacement, gene editing, gene regulation, RNA based interventions, and immune modulating approaches.

They are enabled by diverse vector technologies, including viral and non viral delivery systems, and may be delivered directly *in vivo* or through gene modified cells manufactured *ex vivo*. Collectively, these approaches represent a complex and rapidly evolving class of advanced biological medicines.

Furthermore, many of our gene therapy capabilities also support gene modified cell therapy programs.

- Gene replacement therapies
- Gene editing therapies
- Gene modulation therapies
- Immuno-gene therapies
- Hybrid gene therapies
- RNA-based gene therapies
- *Ex vivo* gene therapies
- Cell therapy vectors

Our services

Method Development

Our method development services establish robust analytical foundations to support gene therapy programs from early development through to commercialisation. We design and optimise customised assays focused on the assessment of critical quality attributes, balancing scientific rigour with practical applicability. Methods are developed with downstream use in mind, supporting efficient progression into qualification, validation, and routine GMP testing.

Method Qualification

Method qualification confirms that analytical methods perform as intended for their defined purpose and development stage. Key performance characteristics—including accuracy, precision, specificity, and working range—are assessed to demonstrate method suitability and data reliability. Qualified methods provide a controlled transition toward full validation and enable confident use in GMP environments.

Method Validation

Method validation establishes analytical method performance for routine GMP application within gene therapy programs. Validation activities are conducted in alignment with ICH Q2(R2) and ICH Q14, with systematic evaluation of accuracy, precision, specificity, linearity, and robustness. Validated methods support batch release, stability testing, and long term product lifecycle management.

Method Transfer

Method transfer services support the compliant and efficient transition of analytical methods between laboratories. We manage structured transfers of both client provided and internally developed methods, confirming reproducibility and performance in the receiving laboratory. Well executed transfers reduce technical risk, maintain data continuity, and support development and manufacturing scale up.

Comparability and Equivalency Studies

Comparability and equivalency studies are designed to demonstrate product consistency following manufacturing, process, or site changes. Using sensitive and orthogonal analytical approaches, we assess critical quality attributes across pre and post change materials. These data driven evaluations support regulatory confidence, minimise development risk, and enable continuity across global gene therapy programs.

Batch/release Testing

Batch release testing is performed on GMP, PPQ, and commercial gene therapy batches to confirm consistent product quality and regulatory compliance. Testing is conducted using validated or qualified methods developed in house or transferred from client laboratories, aligned with USP, EP, and JP requirements. Services include full method lifecycle management, issuance of compliant Certificates of Analysis (CoA), and secure retention sample storage.

Stability Studies

Stability studies are executed to support product development, shelf life assignment, and regulatory submissions throughout the gene therapy lifecycle. We design science based stability protocols in alignment with ICH Q1A(R2) and perform sample storage under long term, accelerated, stressed, and forced degradation conditions. Advanced analytical testing enables meaningful data trending and interpretation to support change management decisions.

Documentation

Documentation services include the generation of client-specific SOPs, study protocols, and technical reports tailored to individual gene therapy programs. All documentation is authored to support GMP activities, analytical testing, and regulatory expectations across global markets. Our controlled, high-quality documentation enables clear data interpretation, traceability, and seamless integration into client quality systems and regulatory submissions.

Our Expertise in Gene Therapies

2018
Expansion of Labs focusing on Biologicals Testing Capabilities

2019
Biosafety Level 2 (BSL2) Labs Open
Establishment of first Gene Therapy program

2020-2023
Expansion of Gene Therapy Testing Capabilities and Method Establishment

2024
Commercial Release of Gene Therapies

2025
Further Lab Expansion of BSL2 areas and Bioassays Testing Capabilities

An Expert Team for your gene therapy - A dedicated, cross functional team ensures scientific continuity, proactive risk management, and on time data delivery

- TECHNICAL CONSULTANT – ADVANCED THERAPIES
- DEDICATED PROJECT MANAGER
- TECHNICAL TEAM LEAD
- ANALYTICAL TEAMS
- QUALITY ASSURANCE TEAM

Every gene therapy program is supported through a collaborative partnership built on trust, transparency, and scientific expertise. We work closely with sponsors to understand program goals, anticipate challenges, and provide proactive, solution focused support.

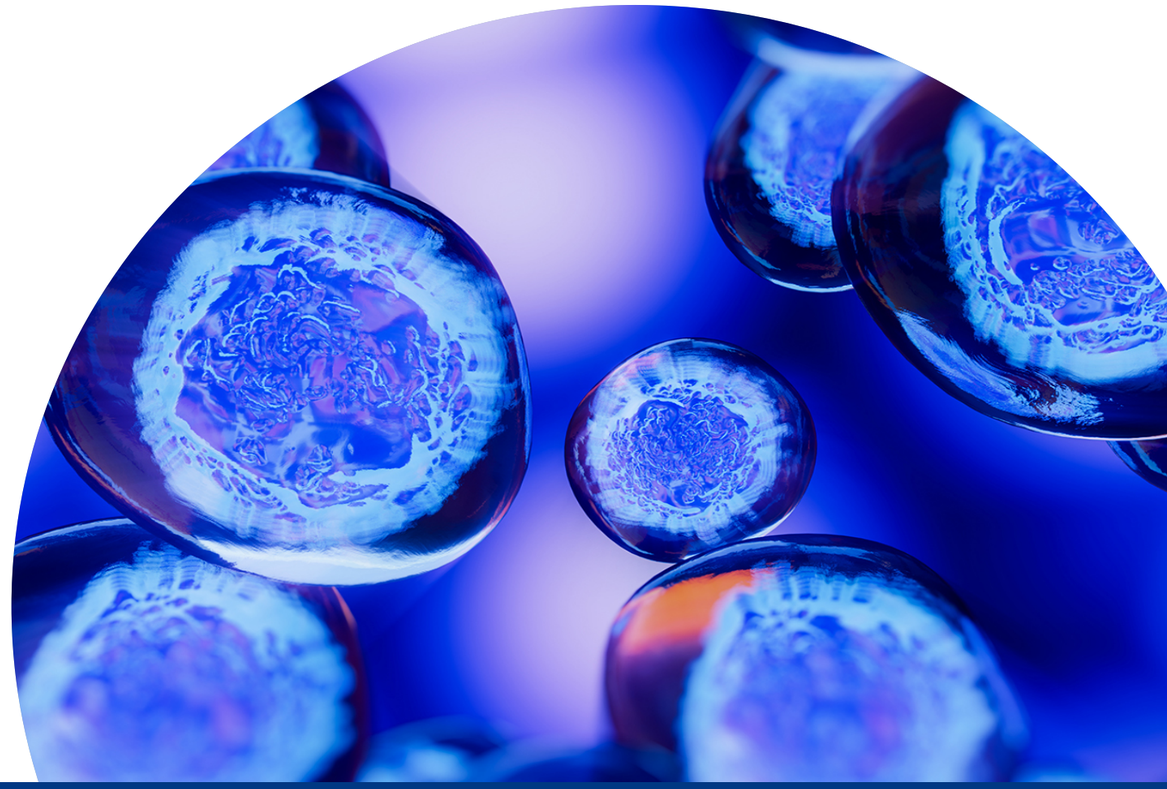
Clear communication and consistent engagement ensure alignment at every stage, from planning through data delivery. This relationship led approach enables confident decision making and long term success across the product lifecycle.

Capabilities for Viral Vector Gene Therapies

COMPENDIAL AND PHYSICAL CHARACTERISTICS	pH	Potentiometry
	Osmolality	Freezing Point Depression
	Appearance	Colour, Clarity, Turbidity, Visible Particulates
	Aggregation	DLS, SEC-MALS
	Subvisible Particles	Liquid Particle Counter
IDENTITY	Gene of Interest ID	NGS, Sanger, ddPCR
	Capsid ID	ELISA, LC-MS (QTOF)
CONCENTRATION	Genome Titre	ddPCR, qPCR
	Capsid Titre	ELISA
PURITY AND INTEGRITY	% Empty/Full	AUC, AEX-HPLC, Photometry
	Purity	CE-SDS, SDS-PAGE, MS, HPLC
POTENCY	Cell based expression assay relating to MOA	Readouts; Western blotting (manual and capillary based), Immunoassay, ddPCR, qPCR
	Infectious Titre (TCID50)	Readouts; CPE, ddPCR, qPCR

Capabilities for Viral Vector Gene Therapies

RESIDUALS AND PROCESS RELATED IMPURITIES	Host Cell Protein	ELISA
	Host Cell DNA	ddPCR, qPCR
	Residual Plasmids	ddPCR, qPCR
	Residual Benzonase	ELISA
	Poloxamer (P188)	HPLC-CAD
	Residual PEI	HPLC-CAD
	Residual BSA	ELISA
	Iodixanol	HPLC
SAFETY	Replication Competency	qPCR, ddPCR
	Microbial Safety, Mycoplasma and Adventitious Agents	Sterility, Endotoxin, NGS, qPCR, ddPCR

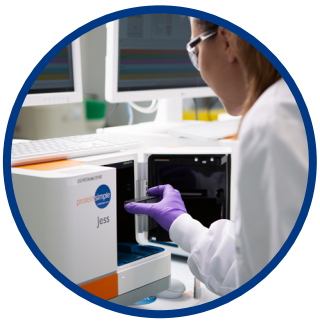


Capabilities for Lipid Nanoparticles

COMPENDIAL AND PHYSICAL CHARACTERISTICS	pH	Potentiometry
	Osmolality	Freezing Point Depression
	Appearance	Colour, Clarity, Turbidity, Visible Particulates
	Particle Size and Distribution	DLS, SEC-MALS, AUC
	Aggregation	DLS, SEC-MALS
	Subvisible Particles	Liquid Particle Counter
	Surface Charge	Zeta Potential by DLS
	Particle Morphology and Structure	NMR
IDENTITY	Gene of Interest ID	NGS, Sanger, ddPCR
	Identity of Lipids	RP-HPLC-CAD, HPLC-MS, NMR
	Identity of Polymers	SEC, HPLC-MS, NMR
	Lipid Content	RP-HPLC-CAD
	Polymer Content	SEC, NMR
PURITY AND INTEGRITY	RNA Size and Integrity	CGE
	% of mRNA fragments	IP-RP-HPLC
POTENCY	Cell based expression assay relating to MOA	Readouts; Western blotting (manual and capillary based), Immunoassay, ddPCR, qPCR
SAFETY	Microbial Safety, Mycoplasma and Adventitious Agents	Sterility, Endotoxin, NGS, qPCR, ddPCR

Capabilities for RNA-based Gene Therapies (mRNA, siRNA, miRNA, gRNA, ASO)

COMPENDIAL AND PHYSICAL CHARACTERISTICS	pH	Potentiometry
	Osmolality	Freezing Point Depression, Vapor Pressure
	Appearance	Colour, Clarity, Turbidity, Opalescence, Visible Particulates
	Subvisible Particles	Liquid Particle Counter
IDENTITY	RNA Sequence Confirmation	NGS, Sanger, LC-MS
	Cap Structure/ Poly (A) Tail	LC-MS, Enzymatic Assays
CONCENTRATION	RNA Concentration	ddPCR, qPCR, UV Spectrophotometry, HPLC
	RNA Encapsulation Efficiency	IP-RP-HPLC
PURITY AND INTEGRITY	RNA Size and Integrity	CGE
	% of mRNA fragments	IP-RP-HPLC
	Double stranded RNA (dsRNA)	ELISA, HPLC
	Residual DNA Template	ddPCR, qPCR
	Residual Enzymes	ELISA
	Residual Solvents/Reagents	GC, HPLC, ICP-MS
POTENCY	Cell based expression assay relating to MOA	Readouts; Western blotting (manual and capillary based), Immunoassay, ddPCR, qPCR
SAFETY	Microbial Safety, Mycoplasma and Adventitious Agents	Sterility, Endotoxin, NGS, qPCR, ddPCR



Contact Us

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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

Full-Time-Equivalent

PSS Insourcing Solutions®

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