

FACT SHEET

ProtaGene's Advanced Analytical Capabilities

ProtaGene is a world-leading analytic CRO partner for the biopharmaceutical and cell and gene therapies industries. From research through commercial product release and testing, we provide the most advanced, integrated, and complete analytical capabilities.

Our best-in-class data packages and test reporting provide scientific, technical, and regulatory support to advance, de-risk, and accelerate all stages of biopharmaceutical development.

Biologic Therapeutics

Expertise in advanced method development, early to late-stage characterization, GMP product testing, and full analytical packages for product lifecycle management, including:

- ◆ Phase Appropriate Product Characterization Pre-IND through BLA
- ◆ Manufacturing and Process Analytic Testing
- ◆ ICH/GMP QC Lot Release and Stability
- ◆ Biosimilar Program Support from Clone Selection through Commercial Release
- ◆ Clinical/*In Vivo* Sample Analytics for Quantitation and Attribute Monitoring

Cell and Gene Therapies

We have been at the forefront of developing DNA/RNA and protein vector analytics to advance gene therapy safety, including:

- ◆ GeneWerk Integration Site Analysis
- ◆ Vector Characterization
- ◆ Bioinformatics - NGS Data Analytics
- ◆ Genome and Gene Editing Analysis
- ◆ Gene Expression Quantitation
- ◆ Immunogenomics

Cell-based Therapies

- ◆ CAR-T (Autologous and Allogenic)
- ◆ Engineered Blood Cells

CORPORATE FACT SHEET

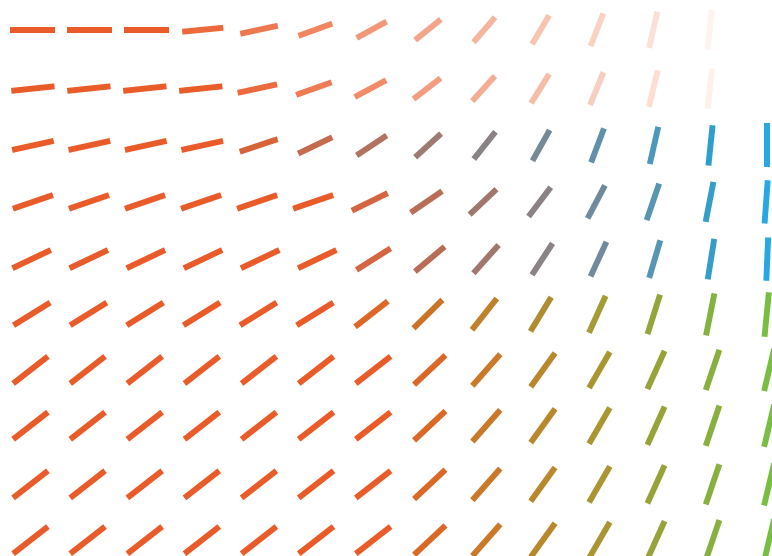
ProtaGene is a Unification of Expertise in Protein, Gene and Cell Therapy Analytics

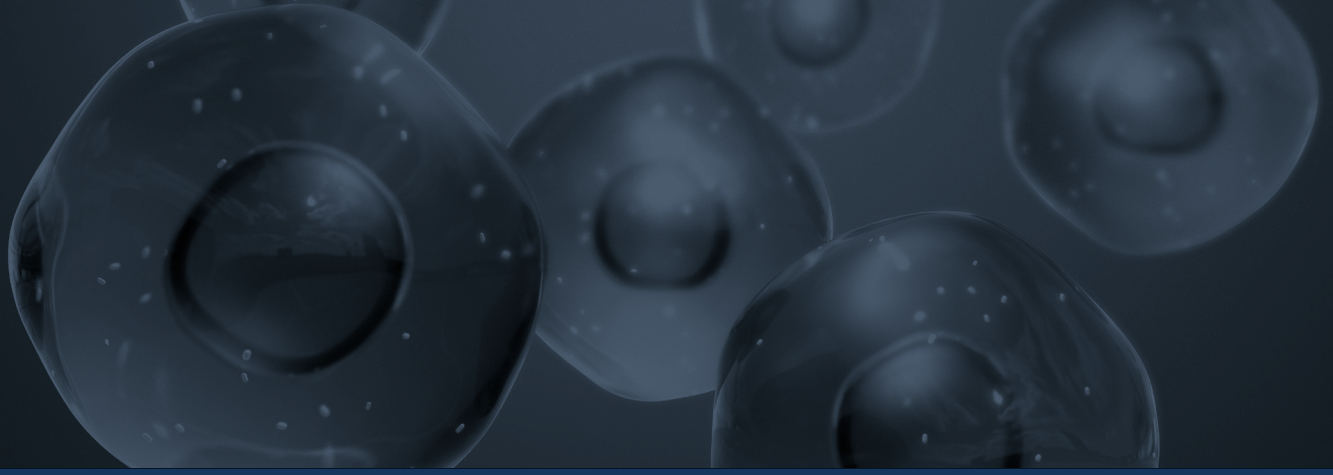
Protagen Protein Services, BioAnalytix, and GeneWerk independently embarked on their journeys in advanced protein and gene therapy-based analytics and then joined together in 2021 to integrate their experience, platforms, and quality processes to help leading pharma and biotech companies accelerate regulatory approval of medicines to treat patients in need.

In this, our involvement and successful accomplishments over nearly three decades have given us the confidence and experience to know that ProtaGene will rise to the challenges of tomorrow's therapeutics so we may continue to help enrich the health and lives of patients around the world.

Biologic Therapeutics Platform Expertise

- ◆ Recombinant Proteins—including Complex, Highly Glycosylated Proteins
- ◆ Multi-subunit Complexes—Protein, Nucleotide, Ligand
- ◆ mAbs
- ◆ ADCs and Protein Conjugates
- ◆ PEGylated Proteins
- ◆ Bispecifics/Multispecifics
- ◆ Fusion Proteins
- ◆ Enzyme Replacement Therapies





Gene Therapy Platform Expertise

Capsid-based Vectors

- ◆ AAVs (Multiple Serotypes and Engineered Vectors)
- ◆ Novel Systems
- ◆ Adenovirus

Non-viral Vectors

- ◆ Polynucleotide (DNA/RNA) Formulations
- ◆ Lipid Nanoparticles
- ◆ Transposons
- ◆ Plasmids

Complex, Envelope Vectors

- ◆ Lentivirus
- ◆ Gammaretrovirus
- ◆ Novel Viruses

Genetic Engineering

- ◆ TALEN
- ◆ CRISPR/Cas9
- ◆ Zinc-finger Nucleases
- ◆ Other Systems

Scope of Operations

- ◆ Four Global Sites throughout Europe and North America
- ◆ Have Supported the Development of over 400 Biologics
- ◆ Established Full Development Program Partnerships with Leading Pharma and Biotech Companies
- ◆ Participated in > 50 Gene and Immune Gene Therapy Clinical Trials
- ◆ Supported AAV (Adeno Associated Virus) Integration Profile for Glybera for Approval of First Gene Therapy Drug in the Western World for Lipoprotein Lipase Deficiency (LPLD)

Quality Management Systems

- ◆ GMP, GCLP, GCP Compliant, GLP Possible
- ◆ Data Integrity and Traceability
- ◆ Equipment Qualification Particularly Computerized Systems Based on Good Automated Manufacturing Practice (GAMP)

Consult with Our Team

Discover how ProtaGene can support your development programs:

info@protogene.com