

## Enabling Today's Therapeutics

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 in advancing 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

- CART (Autologous and Allogenic)
- Engineered Blood Cells

## 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

### Complex, Envelope Vectors

- Lentivirus
- Gammaretrovirus
- Novel Viruses

### Non-viral Vectors

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

### 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:

[contact@protogene.com](mailto:contact@protogene.com)

