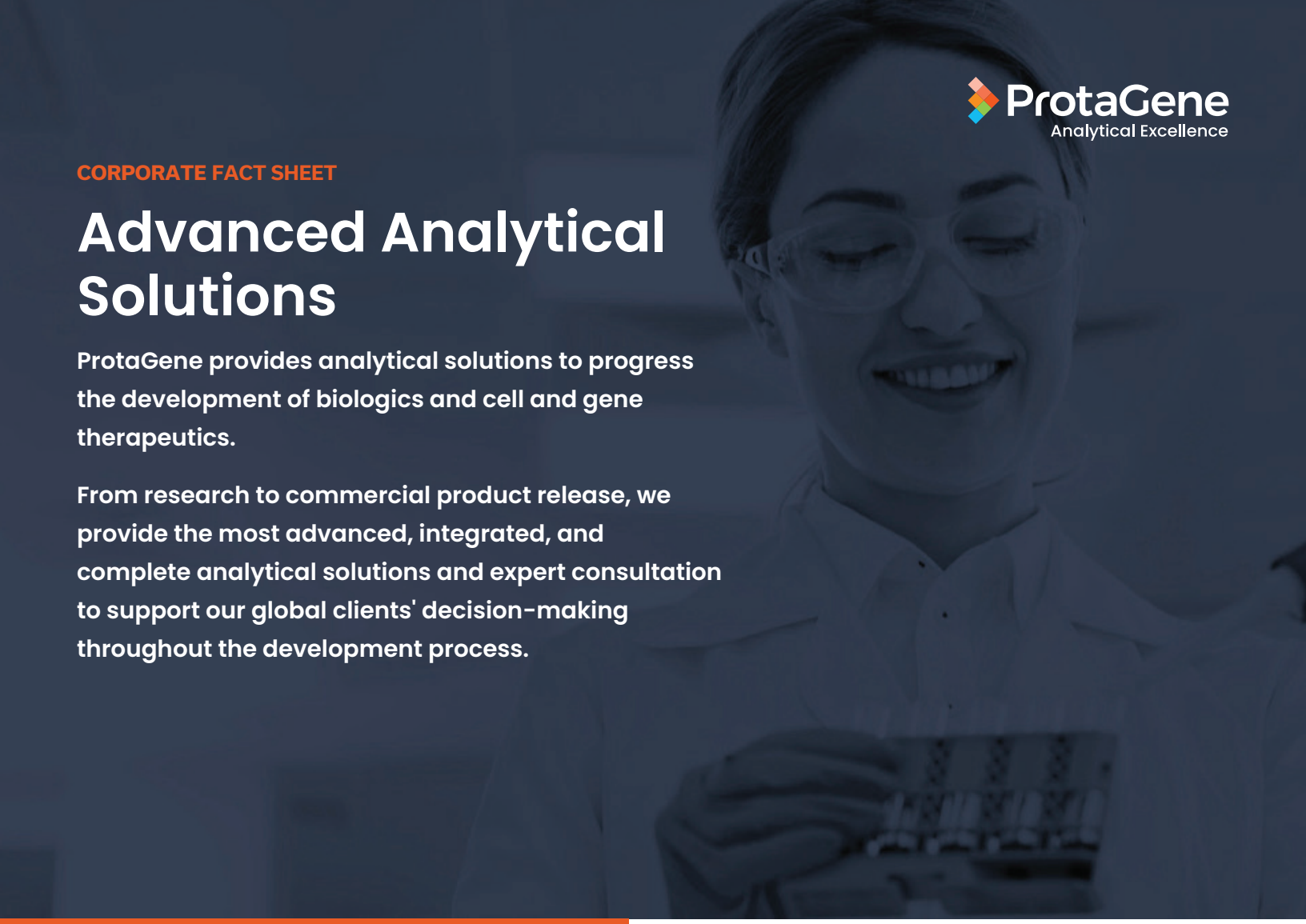
ProtaGene
Analytical Excellence

CORPORATE FACT SHEET

Advanced Analytical Solutions

ProtaGene provides analytical solutions to progress the development of biologics and cell and gene therapeutics.

From research to commercial product release, we provide the most advanced, integrated, and complete analytical solutions and expert consultation to support our global clients' decision-making throughout the development process.



Solutions for Biologic Development

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

Solutions for Cell & Gene Therapy Development

CMC & Product Development

- Enabling Process Development Solutions
- Complex Vector Characterization, CQAs & Correlations
- Custom Process Residuals & Impurity Methods
- Genome & Gene Editing Analysis
- Gene Expression Quantitation

Bioanalysis Support

- Safety Assessments by Integration Site Analysis
- Biodistribution
- Vector Shedding

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Burlington, MA 01803 USA

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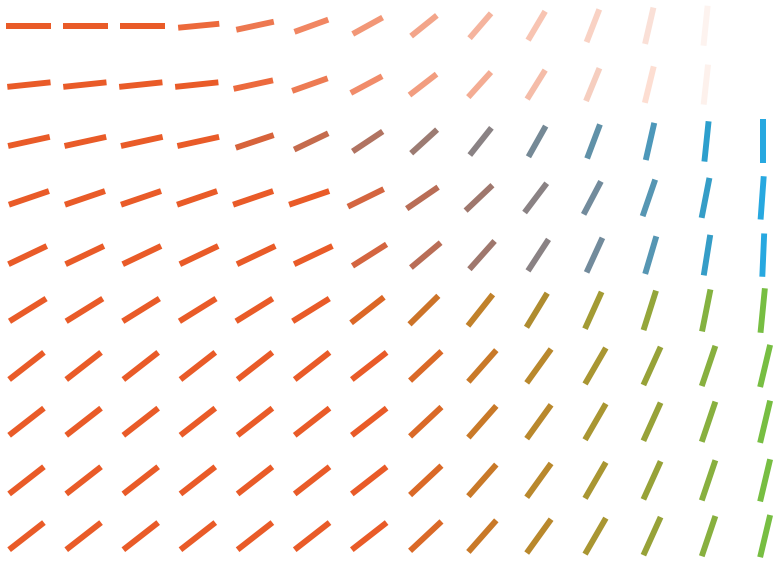
Innovative Analytical Solutions Enabling the Development of Biologics, Gene and Cell Therapy Products

Advanced therapeutic discoveries, technologies, and novel approaches emerge daily, and analytical expertise is the backbone required to achieve commercial success.

The market needed a new kind of analytical solutions partner. In 2021, Protagen Protein Services, BioAnalytix, and GeneWerk joined forces to establish ProtaGene, a new analytical solutions partner that combines their collective experience of nearly thirty years. ProtaGene leverages our team's diverse advanced biologics and cell and gene therapy development expertise to meet the market's current and future challenges—comprehensive solutions, technical platforms, and quality processes allowing pharma and biotech companies to accelerate regulatory approval of medicines to treat patients in need.

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
- mRNA
- Oligonucleotides
- Formulation Development



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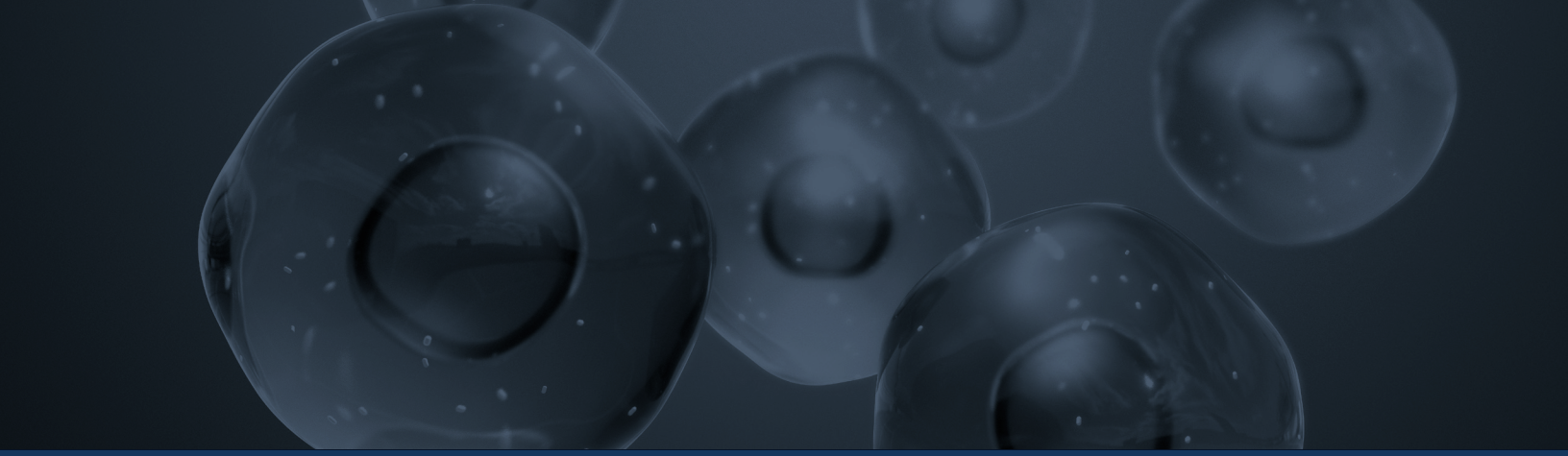

Cell & Gene Therapy Expertise

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

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

Cell-based Therapies

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

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:

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