

# Gene Therapy Development & Manufacturing Services

Pharmaron's Gene Therapy CDMO, located in Liverpool, UK has a 15-year track record in the development and manufacture of gene therapies and biologics. This is further underscored by the completion of multiple late phase development programs and Pharmaron's Gene Therapy ability to deliver next-generation therapeutics from concept to medicine. We offer a full suite of services from plasmid design and cell line development through to clinical manufacture and process characterisation. Our world-class analytical capabilities include state-of-the-art physico-chemical, biophysical and bioassay technologies.

## Capabilities

- 80,000 ft<sup>2</sup> flexible state-of-the-art development and manufacturing
- Scalable suspension culture systems
- Automated cell line development
- Single-use technologies
- Range of bioreactor scales (15mL to 500L)
- Chromatography-based purification
- Pharmaron HEK293 cell line available
- Pharmaron Plasmids including GOI backbone available
- High throughput process development
- Comprehensive analytical toolkit
- Best-in-class product characterisation

## Services

- Product concept to drug substance clinical supply
- Cell bank generation, stability and storage
- Plasmid design, development and manufacture
- Scalable, suspension-based AAV process development
- GMP production moving swiftly from feasibility to clinical grade material via our proven platform process
- Supply of AAV for preclinical, toxicology and clinical studies at a range of scales
- Analytical and product characterisation services
- Bioassay development and testing
- MHRA licenced GMP production suites with supporting QP release
- Authoring CMC sections for regulatory submission dossiers for clinical and market approval (US, EU and global)

