康龙化成 PHARMARON

GENE THERAPY

IND and IMPD-Enabling Packages

Pharmaron is able to support the preclinical and CMC development demands for a new drug candidate to be IND-ready or IMPD-ready for First-in-Human (FIH) clinical trials. Pharmaron's global team of cell and gene therapy drug developers are experienced with authoring regulatory dossiers and interacting with regulators during scientific advice or pre-IND meetings.

Preclinical Testing

- Proof of concept to GLP toxicology studies
- Broad range of disease models in different species with expertise across all routes of administration
- Access to board-certified toxicologists and veterinarians
- Comprehensive suite of bioanalytical assays (NAb, ADA, ELISPOT, biodistribution, shedding, biomarkers)
- Product-based testing strategy with a comprehensive set of analytical platforms

Services

Chemistry, Manufacturing and Control

- **Manufacture of drug substance for preclinical, and toxicology** studies; **manufacture of plasmids** (research and GMP Grade)
- **Analytical and potency assay method development, qualification/validation** to support release of drug product for FIH
- **Stability testing** and shelf-life assignment
- **Manufacture & QC release testing of drug substance and drug product** for clinical studies

Pharmacology/Toxicity

- **Preclinical study design, data acquisition, interpretation, bioanalytical** method development and validation (GLP, Non-GLP)

Regulatory

- **Authoring preclinical, CMC sections** for IND and/or IMPD submission dossiers

CMC Development

- 80,000 ft² state-of-the-art development and GMP manufacturing
- MHRA approved GMP facility
- Animal-free, scalable platform manufacturing process from 15mL to 500L
- Suspension culture and chromatography-based purification
- High throughput process development
- Platform suite of analytics
- Production of critical starting materials (cell banks & plasmids)

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Laboratory Services

Chemistry, Manufacturing and Control

Clinical Development

Biologics & CGT

Pharmaron is a premier R&D service provider for the life sciences industry that offers a broad spectrum of research, development and manufacturing service capabilities throughout the entire drug discovery, preclinical and clinical development process across multiple therapeutic modalities, including small molecules, biologics and CGT products.