康龙化成 PHARMARON

GENE THERAPY

Biologics and Viral Analytics and Characterisation

Pharmaron's Gene Therapy CDMO, located in Liverpool, UK, provides analytical capabilities for analysis of biologics and viral vectors from early phase to market authorisation. Our analytical toolkit supports biological, physiochemical and biophysical characterisation of all biologics product modalities and addresses the unique challenges presented by advanced therapies. Our team utilises state-of-the-art analytical automation to increase sample throughput for process development and characterisation studies.

Capabilities

- Intact mass analysis
- Peptide mapping
- CE-SDS
- AUC
- AEX-HPLC
- Cryo-EM
- Mini-TEM
- ddPCR
- Capsid ELISA
- SEC/RP-LC-FLR
- Mini-TEM
- SEC
- DLS
- DSF
- Sanger sequencing
- Next Generation Sequencing coming soon!
- Infectivity
- Transgene quantity (CBPA, ddPCR)
- Functionality (flow cytometry, microscopy)

Services

- **Method development** with focus on using ultra-sensitive methodologies
- Development of **platform** and **bespoke** analytics including **bioassays** for release, stability and in-process analysis
- Analytical release testing using our **validation ready** AAV and recombinant protein platform analytical release kit
- Phase-appropriate **method validation** and method **transfer**
- **Process characterisation** expedited with use of **high-throughput techniques**
- **Stability** study design, execution and **shelf-life assessment**
- Specialist knowledge in **low endotoxin** recovery studies
- Advanced analytical toolkit for **product characterisation, comparability and forced degradation studies**
- Identification and evaluation of **critical quality attributes**
- Design and justification of phase appropriate **product release specifications**
- Critical **starting materials stability** and **release testing**
- Authoring CMC sections for **regulatory submission dossiers** for clinical and market approval **(US, EU and global)**

康龙化成 PHARMARON
www.pharmaron.com
bd@pharmaron.com

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.