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CELL & GENE THERAPY

Potency Assay Development and Validation

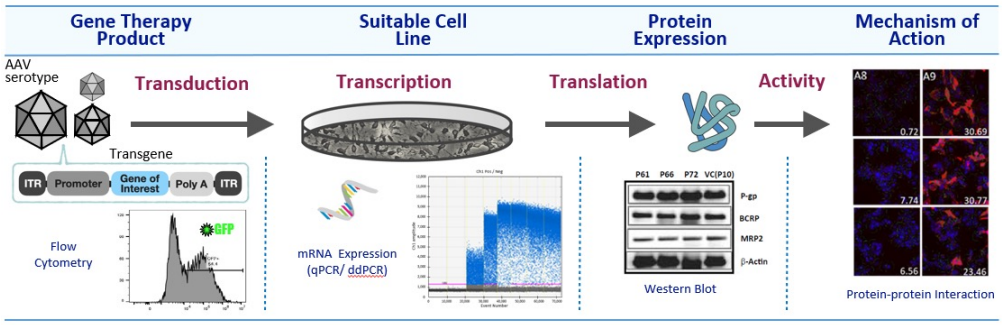
The Pharmaron US team has a proven track record of successfully supporting cell and gene therapy (CGT) programs from preclinical to post market approval. To date, Pharmaron is the only CRO in the United States who has validated a potency assay for an FDA-approved gene therapy product, and we continue to support the batch release testing of this product. Potency is a critical quality attribute (CQA) of any CGT product and a prerequisite for biological license application (BLA) approval and for the release of manufactured lots.

Capabilities

Technology Platforms

- HPLC
- LC-MS/MS
- qPCR/ddPCR
- Ligand binding assays (ELISA)
- Flow cytometry
- High-content imaging
- Western blot

Multi-Step Process Based on Central Dogma of Molecular Biology



- Top-Down Approach for the **Ideal Assay Profile™ (IAP)** leverages any combination (but not limited to): enzyme activity, transporter, transcription factor activation, receptor-mediated signaling pathways, intracellular protein-protein interactions, and more
- Full support of potency assays from **development, optimization, qualification, validation to GMP lot release,** including the generation and maintenance of cGMP master cell banks
- A reliable, experienced and knowledgeable partner with a breadth of models (*in vivo*, *ex vivo*, and *in vitro*), analytical techniques, redundancy in equipment, trained analysts, compliant facilities, and quality systems
- Assay development adheres closely to guidelines from governing agencies (e.g. USP, ICH, GMP, FDA, EMA)

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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.