Biodistribution and Shedding

The Pharmaron US team has over a decade of experience successfully supporting cell and gene therapy programs from preclinical through post approval. We understand the complex bioanalytical methods that need to be developed for cell and gene therapy programs and have the specialized expertise to develop qualify and validate robust assays in compliance with FDA/EMA requirements to support your therapeutic programs.

Capabilities

Technology Platforms

- qPCR, RT-PCR, ddPCR
- ELISA
- HPLC
- LC-MS/MS
- Flow Cytometry
- Western Blot
- Luminex

Preclinical Species

- Mouse
- Rat
- Rabbit
- Dog
- Minipig
- NHP

Quality

- R&D
- GLP
- GCLP

Services

Biodistribution

The aim of biodistribution studies is to determine levels of transgene and its product e.g. proteins, where possible

- Biodistribution assays indicate if the target tissue is transduced successfully by the vector, and if so, how much is present in the tissue

- Biodistribution data required to support first-in-human (FIH) trial

- Samples for biodistribution: blood, plasma, CSF, tissues

Shedding

The aim of shedding studies is to determine the secretion/excretion profile of the virus/vector

- Vector shedding represents a significant safety and environmental concern for replication-competent viral vectors

- Data collected from non-clinical shedding studies is used to estimate the likelihood and extent of shedding in humans and to guide the design of clinical shedding studies

- Samples for shedding: serum, saliva, feces, urine, semen, nasal

Choose an Experienced Partner

Utilize our experience to navigate through challenges, such as off-target amplification, variable sample volumes, potential cross-contamination, optimizing low-yield tissue

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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.