

Potency Assay Capabilities

To support Regulatory requirements Pharmaron's experienced potency team in Liverpool (UK) offer **development of bespoke potency assays** across multiple product classes including; viral Gene Therapies, mammalian and microbial products.

Pharmaron can implement a **traditional approach** for assessing the potency of biological products via a single, quantitative biological assay. However, where this is not sufficient, a **matrix approach** can be used for products with complex mechanisms of action, such as Gene Therapy viral vectors, where a combination of biological assays may be required to characterise different aspects of potency through various stages of the product's lifecycle.



Potency Experience and Capabilities

- Established in-house potency capabilities since 2015
- GMP accredited laboratories for potency release testing
- Biosafety Level 1 and 2 workflows in dedicated laboratory space
- Manufacture of analytical RCB, MCB and WCBs for potency testing
- Experienced in handling a variety of cell lines
- Potency assays established and validated for multiple product classes
- Experienced in regulatory interactions for potency strategy

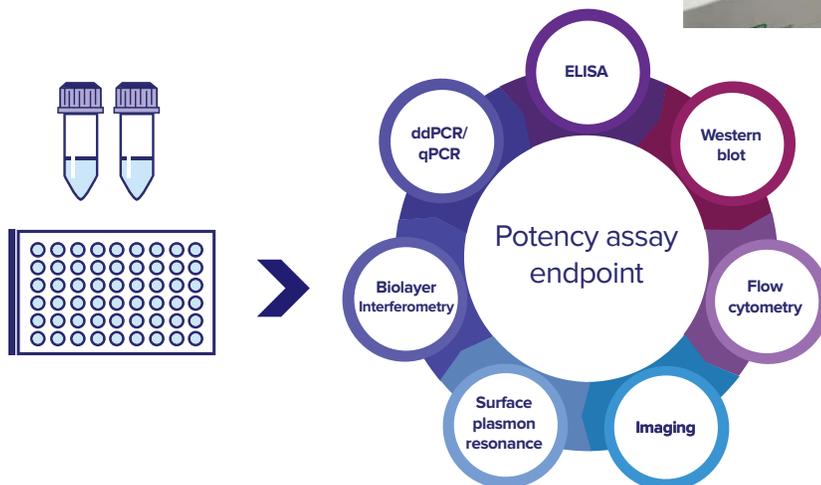
Potency Assays for Gene Therapy Viral Vectors

- Platform ready infectious titre assays for multi-serotype AAV products that target ITR regions
- Infectious titre ITR platform assay can be swiftly optimised to target product's transgene (GOI) region
- Specialist experience in gene expression assay development to target protein or mRNA for transgene quantity
- Effectively developed quantitative gene editing efficiency assays
- Supports bespoke functionality assay development for therapeutic mechanism of action



Multiple Potency Assay Endpoints

Depending on the type of potency assay, Pharmaron has multiple endpoint testing capabilities readily available for both cell-based and ligand binding potency assays.



Generation Of Analytical Cell Banks for Potency Assay Development

Within cell-based assays, the cell itself serves as a critical reagent. The production of analytical cell banks ensure consistency in the cells used for potency assays.



Pharmaron can support in-house generation of Analytical RCBs, MCBs, and WCBs

Research cell banks (RCBs)

- RCBs are 50+ vials (cell line dependent)
- Utilised for assay development, method optimisation and analysis of non-GMP samples

Master cell banks (MCBs) and working cell banks (WCBs)

- Established once development is complete
- MCBs are typically minimum of 50 vials
- WCBs are 50-200 vials (cell line dependent)
- Utilised for phase appropriate validation and analysis of GMP samples for release and stability testing



Laboratory Services



Chemistry, Manufacturing & Control



Clinical Development



Biologics & CGT

BioPotMul0325v1

