

# Large Molecule Bioanalytical Services

Discovery and Regulated Bioanalysis for PK, TK, PD, Immunogenicity, Biodistribution and Biomarker Assays

### **Discovery Phase**

- Rapid method development for discovery bioanalysis
- · Fast throughput sample analysis

#### **Preclinical Phase**

- GLP-compliant method optimization, validation and sample analysis
- IND-enabling programs per ICH/FDA/EMA/NMPA regulatory guidance
- Data packages and reports for IND submissions

#### **Clinical Phase**

- Support for Phase I-III clinical trials
- GCLP-compliant method transfer, validation and sample analysis
- Clinical protocol development
- Clinical trial support for sample acquisition, shipment and logistics

Ligand-binding Assays

**ADA & NAb Assays** 

**Biomarker Assays** 

**Multiplex Immunoassays** 

*in vivo* Tissue Distribution

ADCC, CDC & TDAR Assays

Immunophenotyping









## Driven by Science to Help our Partners Succeed

Discovery Preclinical Clinical Market

**>** Regulatory Support

20 years of experience with global regulatory authorities to meet international regulatory guidelines

Successful Audits

Pharmaron laboratories successfully inspected by FDA, MHRA, OECD, NMPA and EMA

**Experience** 

Hundreds of projects executed and 20+ IND-enabling packages for large molecules bioanalysis submitted per year

Partnering with Your Team

Regular and direct communication with our scientific teams and project managers

## **Drug Types & Analytes**

- Antibodies
- Nanobodies
- Multi-specific antibodies
- ADCs & PDCs
- Oligonucleotides
- Proteins/peptides
- Glycoproteins

- Lipids
- Carbohydrates
- Vaccines
- Polymers
- Biomarkers
- Cell and gene therapy products

## **Technology Platforms**

- ELISA & Hybrid ELISA
- MSD<sup>®</sup>, Luminex<sup>®</sup>, Ella<sup>®</sup>
- Flow cytometry
- qPCR, dPCR, ddPCR
- Liquid chromatography
- Mass spectrometry

- ELISPOT®
- LICOR® fluorescence imaging
- TCR & immunohistochemistry
- IVD and CDx platform
- Gvrolab<sup>®</sup>
- Watson-LIMS® data management

Talk to our scientists about your drug development program today

bd@pharmaron.com www.pharmaron.com

