



# nexelis

**disciplined agility**

assay development • specialty testing

## Unrivaled credentials with large soluble molecules

- Over 15 years of experience in bioanalytical testing
- Over 20 drugs successfully developed and approved
- Over 30,000 PK samples performed
- Over 2M biomarker samples analyzed

## Experience with diversified scaffolds

- Full Ig, Bispecific drugs, peptides, pegylated molecules, enzymes, Fab fragments, nanobodies, etc.

## Regulatory compliance

GLP, GCP, CAP/CLIA

## > BIOANALYTICAL SERVICES

Full range of bioanalytical services required to take large molecule candidate from preclinical to clinical programs (Phase I-IV) using state-of-the-art platforms.

### Pharmacokinetic (PK)

- Multiple species and multiple matrices including serum and plasma
- Deep understanding of the regulatory expectations and intricacies in developing bioanalytical methods
- Different types of PK formats

### Immunogenicity

#### Screening

Antibody isotypes detected are predominantly IgG and IgM and dependent on the route of the drug administration

#### Confirmatory

Specificity assessment of ADAs against the therapeutic protein product are determined by competition in a confirmatory assay

#### Titration

The ADA response magnitude is important as it can impact the pharmacokinetics, pharmacodynamics, safety, and efficacy of the administered drug

#### Neutralizing Antibody Assays

Assays used to detect the ability of ADAs to interfere with the interaction between the therapeutic protein product and its target

#### ADA-Isotyping Assays

Characterization of the ADAs by defining the classes and sub-classes, critical in life threatening adverse events

#### Core Platforms

ELISA (including RIA assays), MSD QuickPlex, VersaMax, Aushon Cira, Singulex Erenna

### Fit-For-Purpose Biomarkers

Over 30 years of experience partnering with the pharmaceutical and biotech industries optimizing study outcomes, accelerating drug development programs, and providing competitive product differentiation in such areas as cardiovascular risk, metabolic diseases, chronic liver disease, drug induced injury musculoskeletal, oncology and inflammation.

- Fit-for-purpose biomarker development and validation
- Esoteric biomarker study and technology transfer
- CAP/CLIA accredited lab for patient testing
- One stop solution to all your needs