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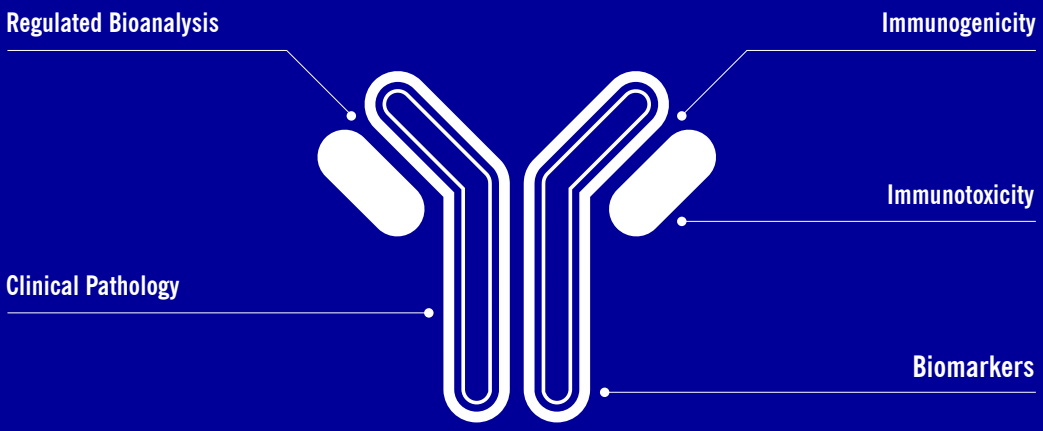
LIGAND BINDING ASSAYS: SUPPORT TO BIOLOGICAL DRUG TESTING IN REGULATED ENVIRONMENT

- High quality service to support biological drugs (mAb, proteins, peptides etc.) across all phases of pre-clinical and clinical development in compliance with GLP and GCP regulations
- More than 10 years of experience to perform activities in regulated environment
- Extensive bioanalytical method development expertise to meet the most demanding and challenging client needs
- State-of-the-art labs and technologies
- Multidisciplinary collaboration to provide an integrated solution to accelerate drug development process



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Bioanalysis plays a critical role in the assessment of biological drug safety and efficacy. Our regulated Ligand Binding Assay group, with state-of-the-art instrumentation and GxP compliant laboratories, has a track record of providing analytical support, for both preclinical and clinical phases of biologics development, dating back over 10 years. We can meet the most demanding and challenging client needs thanks to our scientific expertise, operational experience, and up-to-date knowledge of the regulatory environment. We offer a wide range of activities for analytical solutions in the development process of biologics.

REGULATED BIOANALYSIS

- Method development
- Method transfer of existing validated methods
- Bioanalytical validation following EMA/FDA guidelines
- GxP analysis in support of preclinical and clinical Phase I–III
- Analysis of wide range of sample matrices
- Full quality assurance of study plan and final report

IMMUNOGENICITY

- Development and validation of qualitative and quasi-quantitative assay for ADA
- Three-tier approach: screening (ADA formation), confirmatory (inhibition assay), titration and characterization (neutralizing activity, isotyping assays) that includes statistical cut-point(s) analysis
- Multiple assay-formats: direct or bridging assay (ELISA, ECL-Meso Scale Discovery platform)
- Development and validation of cell-based assay, target binding assay or competitive LBA for detection of NAbs
- Integration of PK and immunogenicity results in preclinical and clinical studies

IMMUNOTOXICITY

- Flow cytometry method(s) development and validation
- Expertise in performing assays in whole blood, PBMCs and purified immune cell subsets
- T, B, NK cells immunophenotyping in animals
- Lymphocyte subsets characterization and activation markers analysis
- *In vitro* assessment of immunoactivation (cytokine release, cell activation/proliferation, cell toxicity assessment)
- *In vitro* studies with human cells (cytokine release, cell activation/proliferation, cell toxicity assessment)

BIOMARKERS (SAFETY and EFFICACY)

- Method development, exploratory or advanced validation
- Preclinical and clinical sample analysis
- In house assays vs commercially available kits
- Single analyte or multiplex panels (eg cytokines/chemokines)
- Proprietary Validated HTT assays in CSF and plasma/PBMC

CLINICAL PATHOLOGY

- Haematology, clinical chemistry, urinalyses and coagulation in preclinical species

SAMPLE MANAGEMENT

- Dedicated team
- Freezer rooms with controlled access and capacity to store about 300K samples at -20°C and -80°C
- Production and supply of sampling kits, labels, study manual for clinical trials

ADDITIONAL ACTIVITIES

- Strong collaboration with our internal Pharmacometrics team for:
  – Clinical PK and PD data analysis
  – Statistical analysis

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