DRUG DEVELOPMENT SOLUTIONS
Part of **Alliance Pharma, Inc.**

Immunogenicity

Immune responses to therapeutic products have the potential to affect Pharmacokinetics (PK), Pharmacodynamics (PD), safety and efficacy.

Our Immunogenicity Centre of Excellence has a wealth of experience in the development and validation of sensitive, specific, selective and drug tolerant assays to measure anti-drug antibody (ADA) responses to therapeutic protein products.

With 20+ years' experience working to GLP and GCP, on a wide range of species and matrices, our flexible and collaborative Immunogenicity Centre of Excellence operates to the highest scientific and quality standards.
We have the capacity, rapid turnaround and logistics needed to support the largest, most complex protocols.

As one of Europe's largest dedicated bioanalytical centres, we support pre-clinical and clinical immunogenicity assessments for a range of products including monotherapeutic antibodies, bispecifics, biosimilars, ADCs, fusion proteins, viral vectors (including pre-screening potential clinical trial applicants) and a wide range of other biological products.

Expertise

- Our team can **advise and interpret** the impact of immunogenicity on PK/PD, especially for therapeutic drugs known to elicit immune responses or where there are pre-existing antibodies
- **70+ Scientists** in our ligand binding team with experience in supporting customers from early preclinical development through to Phase III immunogenicity studies.
- **Fast turnaround** sample analysis of up to 5 days per tier (screening, confirmatory and titre)
- Strong **academic collaboration**

Quality

- Validation performed to **GCP** or **GLP** standards in line with current regulations (**FDA** and/or **EMA**)
- Full risk assessment strategy implemented when new guidance are issued (e.g. FDA 2019 Assay development and validation for immunogenicity testing of therapeutic protein products)
- Full review of validation reports of potential transfer assays with advice provided on alignment with current guidance

Adapted to your needs

Our immunogenicity services can be adapted to your specific requirements:

Science:

We have experience with a variety of analytical platforms (Meso Scale Discovery, AlphaLISA, ELISA, Gyrolab), and use a range of approaches to increase drugtolerance e.g. acid disassociation, ACE, SPEAD and BEAD. We have expertise in characterisation of multi-domain specific immunogenicity responses and isotyping.

Assay development:

Experienced method development team develop assays for screening, confirmatory, titre and nAbs (including cell-based and competitive ligand binding assays).

Collaborative engagement:

Key method development decisions and analytical data are summarised and shared in real time.

Scientific rigor:

Independent Principal Scientist team to ensure the suitability of the method to meet regulatory requirements.

Data & reporting

- A dedicated reporting team to generate reportsto the electronic Common Technical Document (eCTD) specifications
- A validated data transfer utility (DTU) LIMS systems to ensure accurate data transformation compatible with Watson, and Phoenix WinNonlin® ensuring rapid data processing
- Data is managed by our experienced data management team with particular expertise in sample reconciliation and reporting using a combination of Phoenix WinNonlin®, Watson and SAS. We are experienced in providing high quality reports to SDTM/ SEND standards

Statistical support

- A dedicated in–house statistics team with industry leading expertise in the assessment of key parameters including cut point setting, outlier identification, disease state specific cut point comparison, sensitivity and ANOVA, all to the latest industry standards and regulatory guidance

Sample management

- Stand-alone dedicated sample management team, responsible for sample receipt and reconciliation, logging of samples into LIMS, batching for analysis and long term storage
- Robust sample control and traceability from patient to results
- Capability to receive, log and accurately label and sub-aliquot samples for multiple ADA tiers of analysis

Let's discuss your project:

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LEARN MORE

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