PHARMACEUTICAL BIOANALYSIS

BIOANALYSIS SERVICES

Bioanalytical Expertise from Preclinical to Commercialisation

Our Bioanalytical Expertise

Bioanalysis plays a critical role in the assessment of drug safety and effi cacy. We understand that each project presents its own unique challenges, and by applying our nearly 30 years of experience in conducting regulatory bioanalytical studies, our teams work closely with you to ensure that the best possible solutions are delivered, optimizing value for your programs.

With Intertek as your partner, you have access to the scientific and regulatory knowledge of our bioanalytical experts, so that you can leverage the insight we bring to accelerate your drug development.

As time is of the essence, it is important to get your bioanalytical strategy right first time, to meet both regulatory requirements and the challenges presented by complex products and diverse biological matrices.

Helping you to meet your milestones

Our bioanalytical experts have developed methods for a wide range of different compounds, providing phase appropriate, small molecule and large molecule bioanalytical support, high throughput sample bioanalysis, pharmacokinetic and toxicokinetic support, clinical sample management services, immunogenicity and biomarker assays.

Our teams are adept in method development, method validation and transfer of efficient and accurate methods that are optimized for your compound.

With a focus on evolving guidance, our bioanalysis thought-leaders design programs to generate regulatory-driven bioanalytical data to help you meet your next milestone.

To help you to make informed decisions, faster, our Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) compliant laboratories provide clinical kit preparation, sample handling and management, integrated with automated data capture and reporting systems using the latest bioanalytical platforms.

Our experts

Our bioanalysis experts are thought-leaders in their field who actively contribute to progressing the bioanalysis community's knowledge of strategic and regulated approaches for bioanalysis. Our staff routinely present at conferences and contribute to peer-reviewed journal publications.

Our Centre of Excellence and bioanalysis facilities

Our 30,000 square foot European Centre of Excellence is located in Manchester, UK. With continued investment in the latest bioanalytical technologies, our services are positioned to expedite delivery of fast and cost-effective bioanalysis results for global clients involved in preclinical and clinical development of small molecule drugs and biologic medicines.

Diverse bioanalytical technologies delivering the best possible solutions

Our innovative use of bioanalytical technologies means, that no matter how complex your samples are, we can accommodate the chemistry or biology of your analytes as well as any matrix interferences across a diverse array of biological samples. This includes plasma, blood, serum, urine, faeces, spinal fluid, skin, muscle, artery, myocardium, liver and kidney and a variety of tumor types.

At Intertek, we have become experts at adapting analytical techniques to meet the growing demands of the bioanalytical industry, providing our clients with the best possible solutions.

Large Molecule Bioanalysis

We have extensive experience in the development, validation, and sample analysis of quantitative and qualitative GLP and non-GLP immunoassays in support of clinical and preclinical studies for the measurement of therapeutic drugs, synthetic peptides, humanized monoclonal antibodies, chimerics, conjugated drugs, growth factors, hormones, cytokines and biomarkers.

Specialist large molecule expertise

- Quantitative Ligand Binding Assay - Pharmacokinetics
- Immunogenicity Studies using a Tiered Approach
- Cell-based Neutralising Antibody Assay
- Biomarker Solutions
- Enzymatic Assays
- Fluorometric Assays
- Biotinylations and Ruthenium Labeling of molecules
- Mode of Action Studies
- Bioanalytical LC-MSMS for Proteins and Biologics
- Quantification of PEGylated drugs in biological matrices by Nuclear Magnetic Resonance Spectroscopy (NMR)

Expertise across many product types

- Peptides
- Proteins
- Monoclonal Antibodies (mAbs)
- Pegylated Proteins
- Biosimilars
- Biospecifics and Trispecifics
- Antibody-Drug Conjugates (ADCs)
- Growth factors
- Hormones
- Cytokines
- Vaccines

Immunogenicity studies using a tiered approach

Our immunogenicity assay experts are experienced in the development and validation of qualitative immunoassays for the detection of anti-drug antibodies (ADA). They utilize a multi-tiered approach to measuring ADAs, initially all samples are screened for the presence of antibodies specific for the drug, followed by confirmation of the specificity of binding for positive samples. Confirmed positive samples are further characterised by antibody titre assessment, antibody isotyping and for Neutralising antibody (NAb) activity.

We deploy strategic approaches to increase drug tolerance: such as MSD Bridging Mastermix with acid dissociation, ECL/ ELISA based Solid Phase Extraction with Acid Dissociation (SPEAD), Affinity Capture Elution (ACE), "BEAD" (use of nanoparticles or magnetic beads) assays.

Cell-based neutralizing antibody assays are used to detect the presence of ADA which interferes with the biologic activity of the drug. Where the mode of action of the drug is based on target binding a competitive ligand binding assay (LBA) approach may also be used to measure neutralizing antibody activity.

Our GLP and GCP compliant immunogenicity laboratories are fully equipped to meet regulatory and technical standards for immunoassay assessment with platforms such as ELISA, ECL and cell-based neutralization assays.

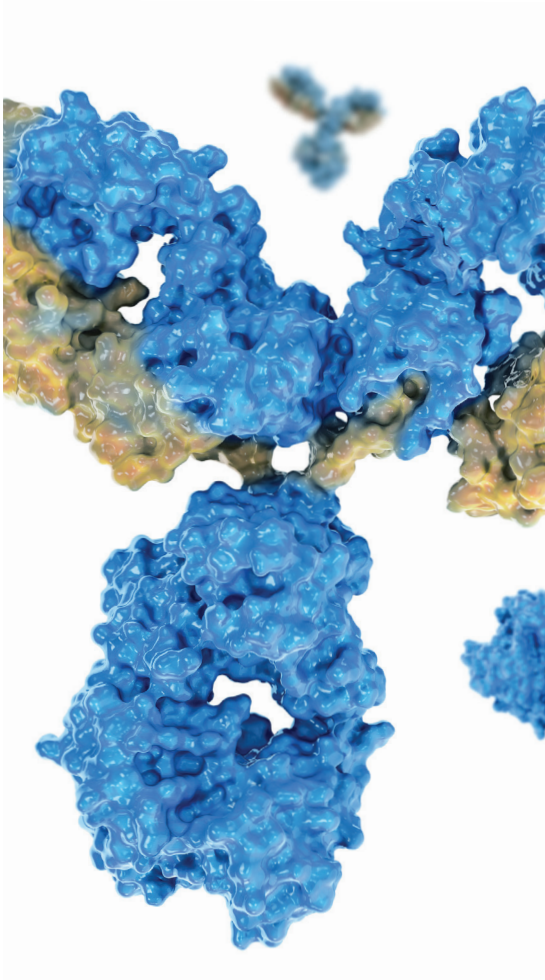
Antibody-drug conjugate bioanalysis

Antibody-Drug Conjugates (ADCs) present unique bioanalytical challenges as they tend to be complex heterogeneous mixtures of multiple species with a range of drug-to-antibody ratios. ADCs typically incorporate both large and small molecule characteristics, and so our bioanalytical teams apply diverse bioanalytical methods, including ligand-binding assays and LC-MS methods, to quantify these species in serum/plasma for PK studies and strategies for assessing immunogenicity. Intertek provides complete bioanalytical capabilities for ADCs:

- Quantitative bioanalytical assays for preclinical and clinical studies
- Total antibody assays
- Total conjugated ADC assays
- Unconjugated (free drug) assays
- Immunogenicity assessment

Biosimilar bioanalysis studies

Intertek's GLP immunochemistry capabilities are world renowned for developing and validating assays for pharmacokinetic (PK), toxicokinetic (TK), pharmacodynamic (PD), immunogenicity studies for biosimilar products.
Using diverse immunochemistry technologies (e.g. ligand binding assays), and functional (e.g., enzymatic and cell-based assays) assay platforms we have experience across a wide range of products including Erythropoietin (Epoetin), Insulin, GCSF, Interleukin, Avastin, Bevacizumab, Trastuzumab, Rituximab, Enbrel, Infliximab, Adalimumab and more.



Biomarker Development And Validation

The assessment of biomarkers in parallel with the efficacy, safety, and mechanism of action of drugs is becoming more prominent with a focus on achieving more efficient and successful drug development.

Biomarker data is extremely valuable as early predictors of drug effects, and can yield important information regarding the dose response relationship, and so can drive insight to achieve successful and efficient drug development. The approach taken to develop and validate a biomarker method should be based on the context of use of the biomarker.

Fit-for-purpose validations are critical to apply to biomarkers which have multiple context of use and therefore it is important not to misapply acceptance criteria used to validate pharmacokinetic assays which have only one context of use to measure the concentration of drug in biological matrix.

Our approach to biomarker validation Intertek's GLP/GCP/GMP compliant laboratories provides support to clients focused on the development of pharmaceuticals and biological medicines. Our biomarker services provide fit-for-purpose validations in support of your context of use. We provide a continuous and iterative process which evolves with your context of use for the biomarker data.

Intertek deploy a diverse array of analytical platforms to support biomarker analysis including ELISA, flow cytometry, cell-based assays, ECL multiplex platforms and high sensitivity measurements by the Quanterix Simoa HD-X Analyzer™.

By establishing and maintaining the consistency of reference standards and controls throughout the duration of the biomarker studies and also screening drug naïve samples whilst taking baseline measurements, our experts build up an understanding of changes in the biomarker data following treatment. This addresses the complexity stemming from the lack of well-defined reference standards and variable pre-existing endogenous levels of the biomarker.

Unique areas of bioanalytical expertise

- Demonstrated Expertise in Ocular Tissue. Bioanalysis for Large and Small Molecules
- Post Marketing Antidrug Antibody (ADA) Assays
- Clinical Kit Prepartation, Sample Handling & Management
- Immunogenicity and Neutralizing Antibody Assays
- Antibody Drug Conjugate (ADA) LC-MS and Immunochemistry Services
- Long History of Bioanalytical Support of Biosilmilar Drug Development
- Excellent Regulatory History

CASE STUDY

Re-evaluating Assays to Minimise Risk and Meet Timelines

The client desired a pharmacokinetic (PK) study to evaluate a potential antibody drug product. We developed a method to analyse the drug concentration in rat serum using a traditional direct sandwich ELISA. However, during development it became evident that, with the proposed reagents and expected parameters, the assay would need to use undiluted rat serum, a potential logistical problem in rodent studies.

Our Solution

Our experts re-evaluated the assay reagents and conditions and were able to introduce a different detection antibody that permitted the use of diluted serum without compromising the sensitivity and quality of the assay.

Benefit Delivered to our Client

Our improved assay, conserved precious samples and minimized the risk of data-loss and logistical problems, allowing the client to meet milestones with high quality data that facilitated their decision making process.

CASE STUDY

Novel Approaches for PEGylated Drugs

A developer of a novel PEGylated drug required a robust and sensitive bioanalytical method which avoided observed issues with sample matrix interference.

Our Solution

Our experts assessed and validated appropriate ^{1}H NMR methods achieving a method suitable for a GLP study. A high-resolution 600MHz spectrometer achieved suitable LOQs whilst presenting a highly specific method for the analyte. Quantitation repeatedly produced statistically accurate results.

Benefit Delivered to our Client

The client was able to progress safety and efficacy studies with confidence in this highly specific and sensitive bioanalytical approach.

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