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Ology BIOSERVICES

Bioanalytical Development and Testing Services

Ology Bioservices' bioanalytical laboratory offers comprehensive bioanalytical services to support pharmacokinetic (PK), pharmacodynamic (PD), and anti-drug antibody (ADA) safety assessments. We have broad biopharmaceutical experience with a variety of large molecules including monoclonal and multivalent antibodies, antibody fragments, proteins, and antibody drug conjugates (ADCs).

- Method transfer and optimization
- Assay development and validation under good laboratory practice (GLP) regulations
- PK/PD ligand-binding methods
- Immunogenicity/ADA assays [screening, confirmation, titration, and assessment of neutralizing antibody (NAb)]
- PK/PD/ADA sample analysis supporting nonclinical and clinical studies
- Singleplex and Multiplex Assays
- Enzyme-Linked Immunosorbent Assay (ELISA)
- Electrochemiluminescence (ECL)
- Radioimmunoassay

Ology Bioservices is committed to providing the highest quality data with fast turn-around time. We keep our Sponsors informed of project progress and are highly responsive to all communications. We are dedicated to earning your trust and being your most reliable drug development partner.

Capable. Collaborative. Creative.

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Bioanalytical Lab Capabilities

The bioanalytical lab at Ology Bioservices has significant experience working with biologic products including biosimilars, vaccines, and biomarkers in different therapeutic areas. Our scientists have extensive experience in bioanalytical method development, validation, and sample testing dedicated to biologics development. Our lab management team members have over 25 years of experience in contract research organization (CRO) environments and pharmaceutical industries. We work collaboratively to effectively meet Sponsor's requirements of accurate, timely, and high-quality data. We have standard operating procedures (SOPs) in place to ensure compliance with good laboratory practice (GLP) and current regulatory guidance documents. Ology Bioservices' bioanalytical lab is routinely audited internally and by Sponsors to the applicable GLP regulations. The result of these audits has proven our deep understanding of regulatory guidelines, and the quality and integrity of our nonclinical and clinical bioanalytical data.

Biopharmaceutical Expertise

Our scientists have expertise in developing and validating ligand-binding assays for biotherapeutics and biomarkers, to provide support from early development to preclinical and clinical studies. Our detail-specific and results-oriented scientists develop, transfer, optimize, and validate ligand-binding assays to meet and exceed our Sponsor's requirements.

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