The background features a large-scale molecular model composed of numerous small spheres. The left side of the image is overlaid with a solid blue rectangle. The spheres are arranged in a complex, branching structure, with the left portion appearing in shades of blue and the right portion in shades of grey.

Large Molecule Bioanalysis



WuXi
AppTec

WuXi AppTec Group's vision is to become the most comprehensive capability and technology platform in the global pharmaceutical and healthcare industry to fulfill the dream that every drug can be made and every disease can be treated.

Our Large Molecule Bioanalysis Service is at the forefront of analytical testing for the next generation of biotherapeutics, helping biotech and pharma companies gain the accurate information they need to advance clinical development as quickly and safely as possible. We are dedicated to maximizing the successful regulatory submission rate for our customers and clearing the path for better, faster, and more effective biotherapies in the pharmaceutical industry.

Large Molecule Bioanalytical Services

WuXi AppTec has facilities in the United States dedicated to supporting large molecule analytical needs of our clients, with skilled scientists focused on the development and execution of the analytical tests our customers need to accelerate development of their large molecule therapeutics.

Capacity

- 18,000 sq. ft in the US
- 25 scientists (7 PIs, 18 scientists in lab)

Compliance

- More than a decade of successful regulatory audits from FDA, EMA and OECD
- Submitted data accepted by worldwide health authorities including US FDA, China CFDA, EMA, PMDA, Health Canada, Australia TGA

Collaboration

- Support over 200 clients, including 8 of top 10 global pharma/biotech companies

One Solution for All Large Molecule Bioanalytical Needs

- In-house development of reagents to analyze biological therapeutic candidates (monoclonal and polyclonal antibodies, recombinant proteins, peptides)
- ISO9001 and AAALAC Certified
- PK assays, immunogenicity assays, biomarker testing
- Bioreagent validation
- Statistical analysis of assay results

Service Support: Preclinical Through NDA/BLA (Non-GLP/GLP)

Pre-Clinical

- Pharmacokinetics (PK) bioanalytical services
- Toxicokinetics (TK) bioanalytical services
- Immunogenicity: (ADA and Neutralizing Antibody (Nab)) bioanalytical service
 - Statistical analysis of cut-point and low positive control determination
- Exploratory biomarker screening/discovery: LBA and LC-MS/MS services
- Reagent generation (IgG and IgY) polyclonal and monoclonal

Clinical

- Pharmacokinetics (PK) bioanalytical services
- Immunogenicity: (ADA and Nab) bioanalytical service
 - Statistical analysis and justification report for cut-point and low positive control analysis
- Pharmacodynamics (PD) biomarker validation (LBA & LC-MS/MS) and screening for clinical samples
- Reagent generation (IgG and IgY) polyclonal and monoclonal

Global Large Molecule Service Platforms (GLP)

Large Molecule Products Supported



Antibody
>50 Programs



Fusion protein
>25 Programs



Recombinant Protein
>40 Programs



ADC
>10 Programs



Peptide (including conjugated)
>25 Programs



Other
>10 Programs

3

Track Record of Experience

PK	ADA	NAb	Biomarker	Total
>100	71	23	>100	135
Validated Assays	Validated Assays	Validated Assays	Validated Assays	Validated Assays
>100	>70	>30	>250	>450
Studies	Studies	Studies	Studies	Studies
>150,000	>80,000	>600	>160,000	>300,000
Samples	Samples	Samples	Samples	Samples

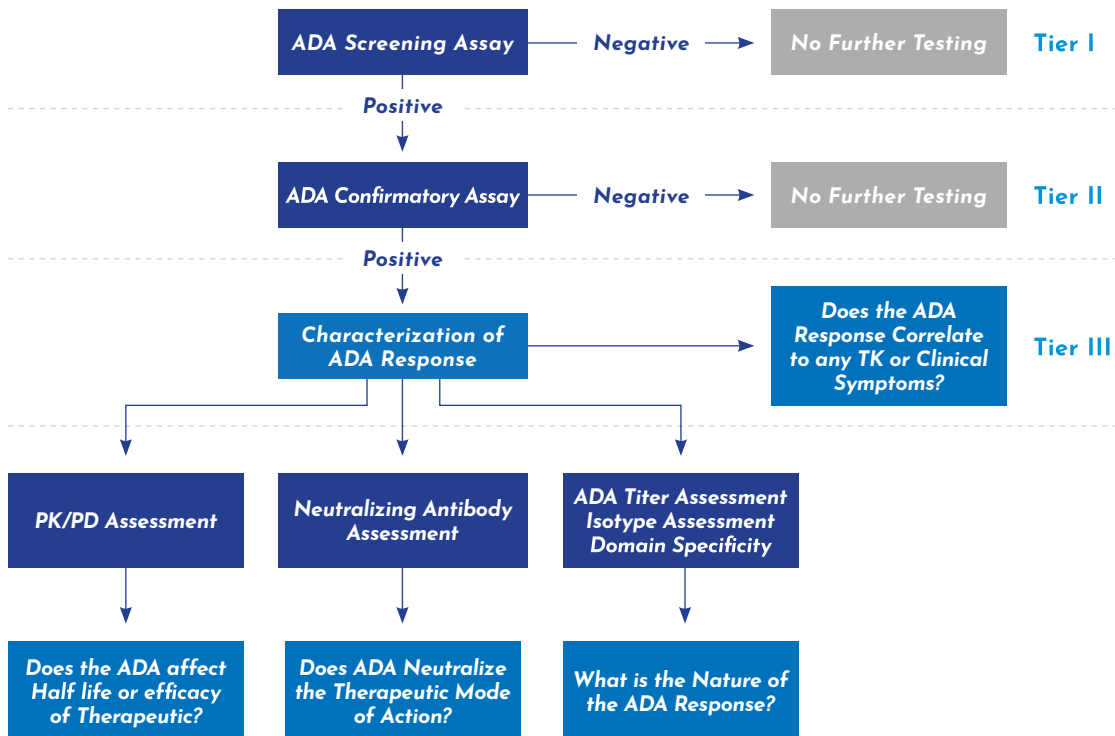
State-of-the-art equipment in North America

- AB Sciex API 6500 high-resolution mass spec
- 1 FACS units
- 2 MSD
- 3 ELISA plate readers
- 1 qPCR, 2 thermocyclers
- Advanced automation systems
 - 1 Tecan EVO automated ELISA workstations
 - 1 Janus
 - 4 Bio-Tek plate washers

Immunogenicity Bioanalytical Services (GLP)

Biologic drugs present many challenges in development. One of which is that they are more likely to trigger the immune system than small molecule drugs, which can lead to unwanted effects. Regulatory agencies require extensive immunogenicity tests, and neglecting this vital element of your IND package can lead to clinical delays. WuXi AppTec collaborates with our clients to develop custom reagents and assays that analyze and predict key measures of immune response, along with expert support in executing the multi-tiered testing that adheres to recent FDA immunogenicity guidelines.

Screening, Confirmatory and Titer Determination Process



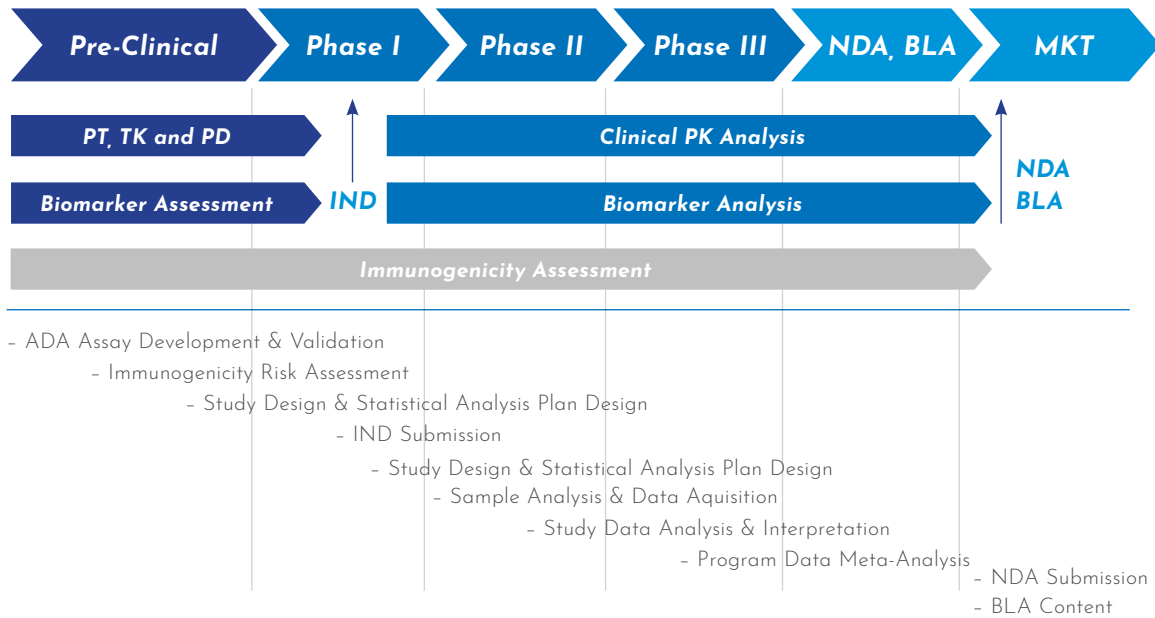
Immunogenicity Bioanalytical Services (GLP)

Services We Provide:

- Reagent generation to fit biological therapeutic using monoclonal or polyclonal IgG and IgY antibodies for positive controls and epitope-specific reagent purification
- Anti-drug antibody (ADA) electrochemiluminescent (ECL) bridging assays with capabilities of executing complex assays with difficult biotherapeutics
- Statistical analysis of cut-point and low positive controls in FDA-acceptable report format
- Non-cell-based neutralizing antibody (Nab) assays
 - High sensitivity assays
 - High drug tolerance with bead extraction and acid dissociation (BEAD)
- Cell-based assays
 - Pharmacodynamic (PD) and functional assays
 - Preferred method for determination of Nab activity by regulatory agencies

5

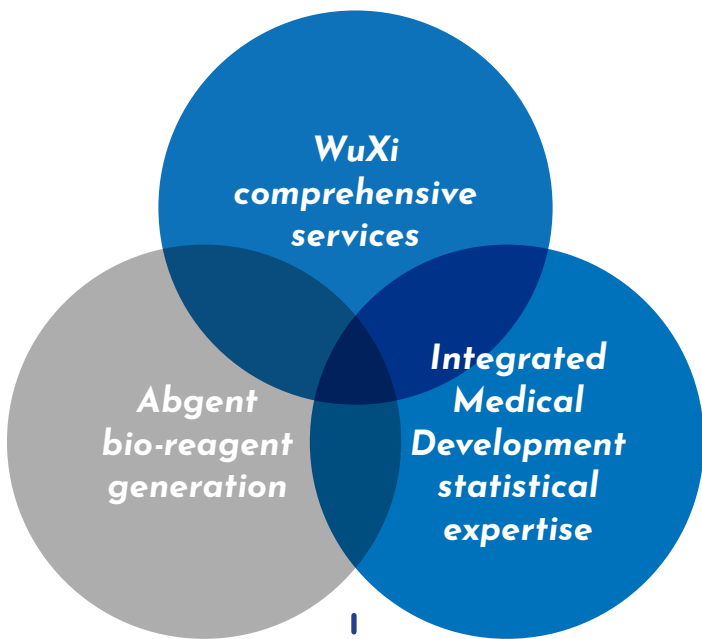
Navigating Through the Immunogenicity Assessment



Immunogenicity Assessment spans pre-clinical through clinical to assess risk for First in Human

How is WuXi AppTec Large Molecule Bioanalytical Service Different?

WuXi AppTec works seamlessly with our partners for bio-reagent generation and Integrated Medical Development for statistical expertise to meet our clients' needs. Clients receive accurate data for their biotherapeutic, with key information they can submit to regulatory agencies, thus reducing the risk of clinical delays.



- Services**
- Bioanalysis Strategy & Planning
 - Chemistry Manufacturing & Controls
 - Regulatory Strategy
 - PK
 - PD
 - Toxicology
 - Reagent
 - Immunology
 - Statistical
 - Biomarker
 - ADA

- Results**
- Accurate, specific data
 - Ready for regulatory submission
 - Reduction in risk of delay



Sample Management

- Global sample receiving capability
- Expedited customs clearance (30-yr experience)
- Dedicated sample/reference management (7/24)
- Complete and secure SRO (sample receiving office) unit
- Centralized temperature monitoring/alarming (phone, email, text messaging @ 24/7)
- Short- and long-term storage available (-20°C or -80°C)

Data Management

- Validated Watson LIMS (Watson 7.5)
- UPS and backup power systems
- Secure electronic data transfer
- Scheduled backup from instruments to dedicated hard disk server
- Periodic restoration test

Quality control

- Validated SOPs
- Harmonization of SOPs across all global sites