



BIOANALYTICAL SERVICES



LARGE MOLECULE ANALYSIS

Our bioanalytical team at Alliance Pharma has extensive experience developing and validating robust LC-MS/MS methods for a wide variety of large molecules including **large peptides, proteins, antibody drug conjugates, and oligonucleotides** in diverse biological matrices.

We have the tools and expertise to analyze your large molecules intact, or digest them into unique signature peptides for highly specific and sensitive quantitative analysis. We specialize in:

- **Regulated (GCP & GLP) and R&D support**
- **Method development, transfer and optimization**
- **Method validation**
- **Sample analysis**
 - All phases (Phase I, II, III, IV) of regulated clinical studies
 - Regulated preclinical TK/PK/PD/DM studies
 - Sample analysis for discovery PK/PD studies & tissue sample analysis

Protein Characterization

As part of a comprehensive suite of bioanalytical services, Alliance Pharma provides protein analysis for structural elucidation and peptide sequencing. Our bioanalytical team has extensive experience using a variety of methods to characterize therapeutic proteins. We provide a broad range of services to meet your regulatory needs. Our protein characterization services are performed according to ICH Q6B guidance.

Protein characterization services offered include the following:

- Protein and antibody characterization
- Peptide mapping
- Disulfide bridge and free sulfhydryl analysis
- N-Glycan profiling
- Monosaccharide composition analysis
- Sialic acid analysis
- Assessment of post-translational modifications (PTMs)
- Intact mass and subunit analysis
- Chromatographic profiles
- Proteomics and glycomics research support
- De novo sequencing
- Native MS of antibody drug conjugates (ADCs) and protein complexes
- Protein identification





Technology Platforms

- Liquid Chromatography
 - Shimadzu HPLC/UHPLC systems with UV, photodiode array (PDA), and fluorescence detection (FLD)
 - Agilent 1290 Infinity II UHPLC with PDA and FLD
 - Dionex UltiMate 3000 RSLCnano with UV
 - Hybrid LBA/LC-MS/MS, Hydrophobic interaction chromatography (HIC), Size-exclusion chromatography (SEC), Ion-exchange chromatography (IEX)
 - Immuno-affinity enrichment, intact protein analysis, enzymatic digestion with surrogate peptides, intact peptide analysis
- Mass spectrometers
 - SCIEX API 4000™, 5500, 6500, and 4000 QTRAP
 - Thermo Scientific™ Q Exactive™ Plus and Orbitrap™ (XL)
 - Agilent 6545XT AdvancedBio LC/Q-TOF
 - Agilent 8900 Triple Quadrupole ICP-MS
- High-throughput sample processing with Hamilton MicroLab Star liquid handlers
 - Thermo Scientific KingFisher magnetic bead processing
 - Thermo Fisher™ Watson LIMS™
 - Certara Phoenix® WinNonlin®

Examples of Large Molecules Analyzed & Characterized

- Glycoproteins
- Monoclonal antibodies (mAb)
- Antibody drug conjugates (ADCs)
- Therapeutic peptides
- Protein complexes

