ALTASCIENCES
BIOANALYSIS & RESEARCH SERVICES

Bioanalysis of Small Molecules using **Mass Spectrometry**

Altasciences Clinical Research is an industry-recognized leader in the bioanalysis of small molecules (Non Proprietary and New Molecular Entities) using mass spectrometry. Our experienced and dedicated scientists work with our sponsors in a collaborative approach. We develop, transfer, and optimize methods with innovative workflows to meet your needs through a tiered approach of selecting a screening, qualified or validated assay. We conduct sample analysis to advance your drug development program from discovery to preclinical to clinical support in accordance or compliance with GLP and current FDA/EMA guidelines. Flexibility, responsiveness, and working closely with our clients allow us to leverage our expertise and capabilities to ensure the optimal path forward for platform selection.

State-of-the-Art Laboratory

Our state-of-the-art, purpose-built bioanalytical facility employs over 100 highly trained specialists who oversee all laboratory functions. Our analysts work mornings and evenings, five days a week (or 24/7 depending on program needs), and are able to process upwards of 60,000 study samples a month. We have designated containment Level 2 (CL2) areas for work with Risk Group 2 (RG2) pathogens, and use the latest equipment and technologies to ensure compliant, on-time regulatory submissions.

Capabilities

- Quantitative analysis using Tandem MS
- Biomarkers and endogenous analytes
- Labile metabolite quantitation
- Microsampling (Mitra® VAMS™ and dried blood spots)

We are experienced with a wide spectrum of biological matrices, including serum, plasma, blood, urine, feces, tissues, cerebrospinal fluid, and vitreous humor.

- Tandem MS supporting quantitation for bioequivalence, 505(b)(2), first-in-human (FIH) and preclinical studies
- Extensive in-house database of over 620 assays
- Strategic method development workflows that consider potential metabolite influences on drug quantitation
- Customized, unique solutions in derivatization, chiral separation, drug stabilization, and multiple metabolite quantitation
- State-of-the-art instrumentation to achieve low quantitation limits with limited sample volume

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Instrumentation

- SCIEX API 5000, 5500 and 6500+ triple-quadrupole MS with SelexION Ion Mobility Technology
- Shimadzu Nexera UHPLC with Sil 30 AC MP Autosamplers
- SPEX Geno/Grinder® 2010 and MP Biomedicals FastPrep-96™ for Tissue Extraction
- Thermo Scientific™ QExactive™ Plus and SCIEX TripleTOF™ 5600+ High Resolution Accurate Mass MS Systems
- Thermo Scientific™ Vanquish™ UHPLC+ focused
- Thermo Scientific™ Dionex UltiMate™ 3000 RSLCnano System
- Hamilton® ID STARlet Liquid Handlers

Support Services

Sample Managemeant and Storage

- Controlled storage units
- Activities and traceability performed using Watson
- Back-up generators for critical equipment
- Three walk-in -20 °c freezers (capacity of approximately 1,430,000 samples)
- 39 stand-up -80 °c freezers (capacity of approximately 1,076,000 samples)
- Sample shipment kit services for multi-site studies

Medical Writing

- Team with over 20 years of experience
- Study design in line with current regulations
- Clinical trial protocol development, review and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

Project Management

- Project Manager (Project Leader) oversees the complete program conduct and deliverables
- Extensive expertise in managing single or multiple site clinical trials, across a wide range of therapeutic areas
- Close collaboration with key internal and external stakeholders ensures seamless and timely communication for successful project completion

Toxicokinetics and Pharmacokinetic Analysis

- Comprehensive preclinical TK and clinical PK and PD data analysis and interpretation
- Robust non-compartmental analysis using WinNonlin® v8 (Phoenix)
- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

Data Management

- Team with over 20 years of experience
- Electronic Data Capture
- CDISC standards fully integrated in workflow
- Medical coding using latest version of medical dictionaries (MedDRA, WHO-DDE)
- Database lock available typically within 2 to 4 weeks of last participant's final visit

Biostatistics

- All programming done using SAS®
- Randomization list
- Statistical analysis plan, including mock TFLs
- Statistical results and appendices (TFLs) for CSR
- Reconciliation of external data (e.g. safety lab)
- Creation of CDISC-compliant FDA submission-ready package

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