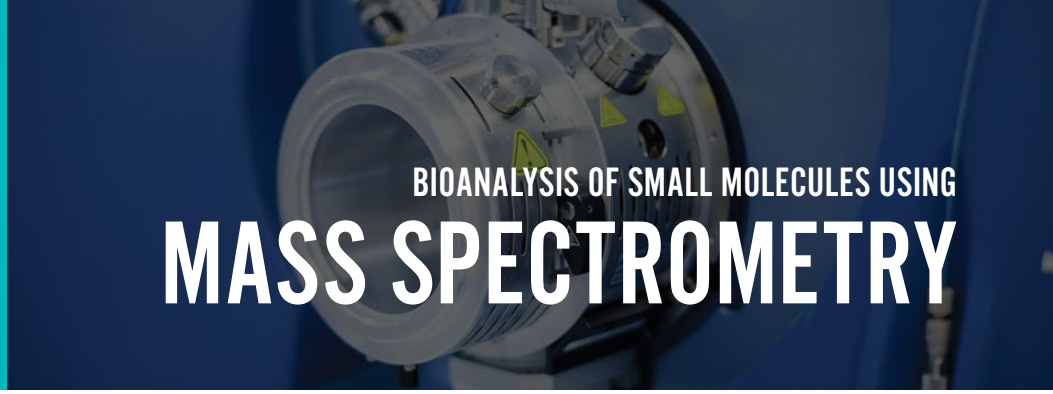
ALTASCIENCES



BIOANALYSIS OF SMALL MOLECULES USING

# MASS SPECTROMETRY

**Altasciences** is an industry-recognized leader in the bioanalysis of small molecules using mass spectrometry. 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 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 260 highly trained specialists. Our analysts can work 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 areas for work with Risk Group 2 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, animal tissues, cerebrospinal fluid, human tissue biopsies, tears, saliva and vitreous humor.

- Tandem MS supporting quantitation for:
  - bioequivalence
  - 505(b)(2)
  - first-in-human (FIH)
  - preclinical studies
  - Phase II and III
- Extensive in-house database of over 685 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

contact@altasciences.com
**altasciences.com**

## Instrumentation

- Over 30 LC-MS/MS instruments, including SCIEX API 5000, 5500, 6500+, and SelexION with Nexera UHPLCs
- HRMS including the SCIEX API 6600, and ThermoFisher Q-Exactive
- Microflow and nanoflow capabilities for the front end of our HRMS systems
- SPEX Geno/Grinder® 2010 and MP Biomedicals FastPrep-96™ for Tissue Extraction
- Hamilton® ID STARlet Liquid Handlers

# Research Support Services

## Sample Management 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)
- 47 stand-up -80 °C freezers (capacity of approximately 1,076,000 samples)
- Sample shipment kit services for multi-site studies

## 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

## 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)

## 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 two to four weeks of last participant's final visit

## 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

## 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

**Manufacturing and Analytical Services**
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