



**DRUG DEVELOPMENT
SOLUTIONS**

Part of Alliance Pharma, Inc.

Bioanalysis of Small Molecules

We are industry leaders in providing integrated bioanalytical support from early discovery to late phase clinical trials recognised for our leadership in science and technology.

As one of the largest dedicated bioanalytical centres in Europe, we continue to pioneer new applications of LC-MS/MS such as biomarkers, proteins and peptides and apply novel technologies to help answer your analytical challenges.

With 20+ years working to GLP and GCP, on a wide range of species and matrices, our flexible service operates to the highest scientific and quality standards partnering with you on your Pharmacokinetic (PK) and Pharmacodynamics (PD) requirements. We have the capacity, rapid turnaround and logistics needed to support the largest, most complex protocols.



Facilities

- » **7,000+ m²** bioanalytical facility in Cambridge (Fordham), UK
- » **20+ GLP/GCP regulated** UPLC-MS/MS systems including the latest technologies



Quality

- » **50+ years** providing bioanalytical services
- » **20+ years** GLP and GCP accreditation



High capacity, flexible service

- » Up to **18,000 samples** performed per month
- » Dedicated single point of contact for each project
- » Logistics and sample management team to support multi-site, global studies including sample collection kit production



Expertise

- » **60+ dedicated scientists** specialising in LC-MS/MS assay development, validation and sample analysis
- » **Pioneering application** of LC-MS/MS for PK and biomarker assays
- » **Broad experience across molecule types** including small molecules, peptide and proteins (Protein LC-MS)
- » Strong **academic collaboration**



Our bioanalytical services

- » Method **transfer**, **optimisation** and **cross validation** of your methods
- » Method Development for **GLP TK** studies and **GCP** clinical trials
- » **Fast method development** for discovery compounds
- » Validation for **GLP** and **GCP** studies
- » High throughput analysis to support **discovery** TK/PK/PD studies
- » Support for regulated **pre-clinical TK studies**
- » **Fast turnaround** for Phase I Clinical Studies
- » Bioanalytical and **PK** support for **clinical studies**, including Bioavailability Studies, Bioequivalence studies and drug-drug interaction studies
- » **Biomarkers** by LC-MS/MS
- » **PK data analysis** using validated software systems (e.g. WinNonlin)
- » **Logistical support** for clinical sample management including production and supply of sampling kits, labels, investigator manual and shipping
- » **Data management** using LIMS or specialist software

Our experience includes

- » New chemical entities (NCE's)
- » Small molecule biomarkers
- » Metabolites and multi-analyte methods
- » Chiral compounds
- » Generics and over the counter (OTC) medicines
- » Comparator drugs and P450 probe substrates
- » Protein and peptide analysis using our unique BioMS™ service – mass spectrometry without the need for synthesis of antibodies
- » Microsampling
- » Assessment of plasma protein binding

Latest technologies

- » ESI and APCI systems
- » SCIEX-4000™, 5000™, 5500Q-Trap™, 6500+™ and TripleTOF® 6600 LC-MS/MS
- » Waters ACQUITY UPLC®, Classic, I-class and H-class systems
- » Waters Xevo TQ-S LC-MS/MS
- » Waters Synapt G2 QTOF system
- » Thermo Quantum Vantage
- » Watson™ LIMS
- » Hamilton STAR-LET liquid handling robotic system
- » TECAN Resolvex A200 sample preparation platform
- » Kingfisher Flex automation of bead-based workflows

High quality reporting and data management

- » Rapid turnaround of analytical data, draft and final reports, using our templates or yours
- » Specialist software to support SEND/SDTM data requirements
- » eCTD compliant reports
- » PK/TK profiling and reporting using WinNonlin™
- » Certified as GLP and GCP compliant by MHRA, successful EMA audits
- » Dedicated independent Quality Assurance, pharmacokinetic and data management personnel

Communication

Our bioanalytical teams comprise of dedicated experts in small molecule bioanalysis. We pride ourselves on our accountability, efficiency and clarity of communication facilitated through a single point of contact.

We have a committed method development team to overcome potential challenges and strive to ensure that our labs are an extension of your company to deliver seamless support of your drug product.

Let's discuss your project:
drugdevelopmentsolutions.com
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