Bioanalytical Sciences

Overview

Since 1990, Worldwide Clinical Trials Bioanalytical Sciences has built its reputation on providing quality bioanalytical services with rapid turnaround at competitive prices. With the most modern bioanalytical instrumentation and over 2,000 validated methods, our state-of-the-art facilities and knowledgeable staff are at the forefront of bioanalytical method development. We can develop a custom method for your drug candidate, modify your existing method or simply transfer and validate your current assay. With assays capable of measuring sub pg/mL plasma concentrations, WCT is well-equipped to handle even the most potent drug candidates.

Our bioanalytical labs are completely GLP-compliant, from SOPs to validated computer systems, in-process inspections and audits. Our Quality Assurance (QA) Unit is charged with monitoring daily activities to ensure FDA conformity. Quality control reviews are performed for data and reports (validations, sample analysis studies) to confirm that the overall quality meets industry standards and is compliant with SOPs.

Clients are assigned a Project Director who works closely with them to ensure that their requirements are met. Highly trained laboratory staff executes their work under close management supervision, with the final integrated product being thoroughly reviewed. High standards, excellent training, and proper oversight are fundamental to WCT. The quality of our work begins with method development and progresses through assay validation and sample analysis.

Bioanalytical Services

Worldwide Clinical Trials Bioanalytical Sciences routinely supports animal pharmacokinetic (PK) or toxicokinetic (TK) analysis for GLP studies. Our laboratory pays particular attention to eliminating carryover and contamination, aiding in the accurate assessment of the no adverse effect level. Our sensitive and rugged methods allow precise measurements with a minimum volume of blood or plasma, and we are experienced in microsampling and dried blood spot analysis.

We support exposure measurement in all types of clinical studies, including the fast export of Watson LIMS results to bioanalytical or PK analysis reports. In addition to plasma, blood and urine assays, the laboratory has experience with CSF and other rare matrices. Laboratory capacity is more than adequate to support fast turnaround in single or multiple ascending dose studies as well as large, first-to-file bioequivalence studies.

Biomarker Services

Biomarker Services complement our pharmacokinetic modeling and clinical trial management services with assays of endogenous compounds. We have some of the most sensitive assays for CNS biogenic amines, capable of accurately measuring the up/down regulation of endogenous neurotransmitters in plasma and CSF. We routinely support the measurement of low levels of steroids using novel approaches of derivatization and LC-MS analysis. We also have fully validated assays of retinoids, selected lipids and peptides. WCT uses selective depletion of matrix, surrogate matrix and surrogate analyte approaches, along with a full complement of validation testing to ensure accurate assessments of biomarkers. All LC-MS assays employ stable label internal standards and have been validated to global regulatory standards.

KEY SERVICES

- CNS
- Cardiovascular and pulmonary
- Metabolic diseases
- Virology
- Oncology
- Narcotic analgesics
- Biomarkers
- Retinoids and Steroids
- Peptides and Oligonucleotides
- Multi-analyte assays
- Enantioselective (chiral) assays
- Low-level quantitation
- Derivatization, immunoprecipitation and enzymatic hydrolysis
- Mass balance, metabolite profiling and identification
- Microsampling including dried blood spots
- Automation
- LC-MS/MS

QTRAP 6500

WORLDWIDE CLINICAL TRIALS
SCIENTIFICALLY MINDED · MEDICALLY DRIVEN

Technology

Our bioanalytical capabilities are supported by Thermo Electron Watson™ LIMS, a highly specialized software system designed to provide compliance with GLP and 21 CFR Part 11 regulations. Beginning with flexible study input, Bioanalytical Sciences uses Watson™ for sample management, analytical run planning, instrument interfacing, assay performance evaluation, data analysis and reporting. Additionally, automated data transfer from Watson™ to Pharsight WinNonlin™ maintains Part 11 compliance for pharmacokinetic analysis and expedites the completion of PK/TK reports. Other export capabilities are also available to provide data in various formats.

Study reports are produced for easy incorporation into electronic submissions. Liquent InSight Publisher™ applies PDF rendering technology to automatically compile source documents with varying file formats into one seamless publication. Additionally, our laboratory utilizes NuGenesis™ software for electronic capture of representative chromatography to meet industry guidelines. These technologies support Part 11 compliant data reporting from Watson™ and other software programs.

WCT has extensive automated sample and liquid handling capabilities including the Hamilton STAR or STARlet and Tomtec Quadra 4 SPE units for sample analysis. These robotic workstations offer parallel processing with the latest feedback technology to ensure a high degree of accuracy and precision. WCT has also automated a variety of method development activities, utilizing the flexibility of the PE MultiProbe and Tecan liquid handlers. We apply the latest extraction, separation and detection technologies to develop high quality assays. Twenty state-of-the-art LC-MS/MS systems operating under Analyst V1.6 are used. A thorough assessment of prior knowledge of drug properties is secured, including requirements for metabolic and population specificity. Methods are optimized and undergo extensive assessment of failure points prior to issuing the test method for validation. The test method and our SOPs are generally sufficient for the validation. However, execution under a client-directed validation plan, including cross-validation or conformance assessments, is also possible.

Equipment

LC-MS/MS Laboratories

Our commitment to our clients is to stay at the forefront of technology, providing the fastest, most accurate results possible. Each of our systems is interfaced to computers running Analyst™ acquisition/processing software. Processed data is transferred seamlessly to our Watson™ LIMS for reporting.

- (1) Sciex QTRAP 6500 triple quadrupole LC-MS/MS
- (8) Sciex API 5000 triple quadrupole LC-MS/MS
- (11) Sciex API 4000 triple quadrupole LC-MS/MS
- (10) Shimadzu Nexera UPLC systems
- (5) Waters Acquity UPLC systems
- (5) Thermo Aria LX2 (Shimadzu-CTC PAL) multiplexed HPLC systems
- (5) Tomtec Quadra 4 liquid handling systems
- (2) Hamilton STAR liquid handling systems
- (2) Hamilton STARlet liquid handling systems
- (1) PE Multiprobe IIEX liquid handling system (method optimization)
- (1) Tecan Genesis RSP 200/8 liquid handling system (plate-based assays)

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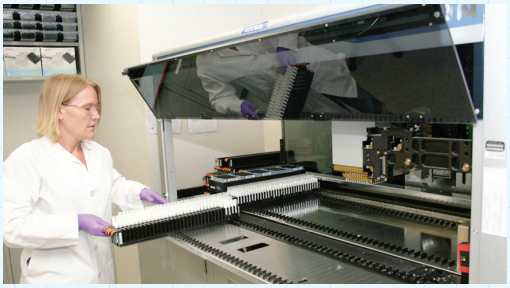
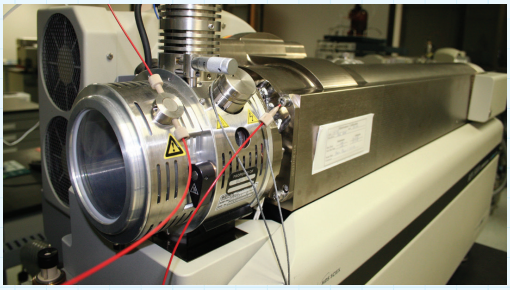


Hamilton STAR liquid handling system



Sciex API 5000

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