Worldwide Clinical Trials

Make Informed Decisions, Faster

With Worldwide Clinical Trials' Bioanalytical Laboratory

What sets our bioanalytical lab apart?

For more than 15 years, Worldwide Clinical Trials has been a trusted market leader in bioanalysis. Our scientific heritage not only means we have accessible expertise to work closely with you, but also means we are compulsive about quality. Our new state-of-the-art facility was constructed with a holistic vision of bioanalytical service requirements, encapsulating both large and small molecule processing combined with powerful analysis tools, including multiple bioanalytical platforms.

Our bioanalytical lab is flexible in productivity and can accommodate analysis based on your study's requirements. State-of-the-art instrumentation and more than 2,400 validated assays make Worldwide industry leaders in bioanalytical method development and validation. Our bioanalytical work meets all regulatory standards, including:

- FDA Regulations (US Code of Federal Regulations, 21 CFR) for Good Laboratory Practice, Good Clinical Practice (GCP), Bioavailability and Bioequivalence Requirements, conduct of clinical trials, and human subject protection.
- European Clinical Trials Directive 2001/20/EC and Commission Directive 2005/28/EC
- UK Medicines and Healthcare Products Regulatory Agency (MHRA) requirements

Bioanalytical Support Services

- Drug discovery
- Nonclinical toxicokinetic studies
- Pharmacokinetic (PK) screening
- Preclinical animal and clinical sample analysis
- Clinical PK /Bioavailability studies
- AME
- Plasma protein-binding studies
- Pharmacogenomics screening
- Method development
- Method transfer
- Method qualification
- Method validation
- Sample analysis

New State-of-the-Art Bioanalytical Facility

- → 60,000 sq. ft. laboratory building located in Austin, TX
- → GLP and Part 11 Compliant; Support Regulated Bioanalysis (Clinical Studies, GCP)
- → Successful FDA Inspection History
- → One hour travel time by car to our 200-bed Clinical Pharmacology Unit
- → End-to-end bioanalytical service as our lab assists with critical reagents generation, labeling, and characterization, TK/PK data analysis and report preparation
- → Capacity to accommodate your bioanalysis needs immediately

Deep Bioanalytical Expertise

- Established group of analytical chemists & method development scientists
- Seamless assay development and validation on a variety of bioanalytical platforms
  - Validated assays with required sensitivity including low pg/mL LLOQs
  - Use stable isotope-labeled internal standard(s) for accurate quantitation work
  - Experience validating analytes of interest in plasma, serum, CSF, and other matrices
- Extensive experience supporting FIH SAD and MAD studies
- Small molecule and peptide therapeutics
- Biomarkers
- Multi-analyte assays, including metabolitesSteroids
- Retinoids
- Unstable analytes, including prodrugs
- Enantioselective assays
- Low-level (sub pg/mL) quantitation
- Derivatization
- Immunocapture and enzymatic hydrolysis
- Microsampling, dried blood sample analysis (VAMS®, Mitra® cartridges)
- Bioanalysis of tissues, CSF, synovial fluid for site-of-penetration and target organ studies
- Large molecule biologics modality:
  - Monoclonal antibody
  - Antibody drug conjugate
  - Bispecific antibody
  - Fusion protein
  - Enzyme
  - Oligonucleotide
  - Gene therapy
  - Pharmacodynamic biomarkers

Industry Leading Equipment & Instrumentation

- More than 20 mass spectrometry instruments for high-throughput LC-MS/MS GLP bioanalysis
- Spectramax
- MesoScale Discovery (MSD)
- Thermo Scientific Orbitrap Hi-Res Mass Spec
- Extensive automation suite with variety of robotic liquid handling workstations and microplate management systems
- Liquid scintillation counter & oxidizer to support radiolabeled AME studies

Our new facility, coupled with our proven history of providing timely, reliable bioanalytical services, is further enhanced with fast access to industry-leading experts to consult and optimize the delivery of the data you need to make informed decisions, faster.

Want to learn more about our bioanalytical capabilities or take a tour of our new facility?

Discover More ⟶

Meet Your Partners

Our industry thought leaders and seasoned professionals are ready to consult and advise your next project to optimize data and give you the competitive advantage you deserve. Meet a few of our team members:

Dr. Tom Zhang

Chief Scientific Officer, Large Molecule Bioanalysis

Our large molecule bioanalytical lab is headed by Dr. Tom Zhang, industry recognized large molecule bioanalysis expert. Dr. Zhang is responsible for:

- Evaluating and recommending analytical platforms in support of quantitative large molecule work
- Actively promoting technical development programs to keep Worldwide at the forefront of technology in support of large molecule bioanalysis
- Maintaining state-of-the-art knowledge pertaining to large molecule bioanalytical methodologies

Dr. Leimin (Perry) Fan

Associate Director, Method Development

Perry has worked in the pharmaceutical industry for more than 27 years and is experienced in analytical support in CMC development, ADME, preclinical and clinical bioanalysis. His current responsibilities at Worldwide Clinical Trials are:

- Leading the method development group to generate robust and sensitive analytical methods to support sponsors' preclinical and clinical studies
- Leading the efforts in the bioanalysis lab on improving automation and introducing new technologies
- Supporting validation and production on troubleshooting and process improvement

Dr. Jason Hamilton

Associate Director, Method Validation

Jason has nearly 20 years of laboratory experience spanning clinical, research & development, and analytical testing laboratories, along with five years of experience managing laboratory teams. His experience includes:

- Leading the method validation group at Worldwide to ensure robust and sensitive analytical methods are in place to support sponsor studies
- Setting-up and leading analytical testing, purification, production, and development operations as well as the quality program for a medical cannabis operation
- Developing methods for the analysis of biomolecules and pharmaceuticals

About Worldwide Clinical Trials

Worldwide Clinical Trials (Worldwide) is a leading full-service global contract research organization (CRO) that works in partnership with biotechnology and pharmaceutical companies to create customized solutions that advance new medications – from discovery to reality.

For more information on Worldwide, visit www.Worldwide.com or connect with us on LinkedIn.