

M E D P A C E

**BIOANALYTICAL LABS****Experts. Experience. Execution.****Discover the POWER OF X™**

**Finding a global CRO with a central campus and lab, a CPU and expert scientists that can deliver the bioanalytical services you need isn't easy.**

**That's why you can trust Medpace Bioanalytical Laboratories.**

**Only Medpace can provide the expertise necessary to complete difficult one-of-a-kind assays and support early phase projects anytime, anywhere.**

**The Medpace Advantage**

Early Phase drug discovery demands not only therapeutic expertise in program development, but a group of full-service partners to deliver exceptional laboratory services quickly and efficiently. Partnering with Medpace as a full-service clinical research organization (CRO) can provide full service capabilities for studies requiring bioanalytical analysis, central laboratories, and clinical pharmacology. All Medpace laboratories are centrally located, adjacent to Medpace Clinical Pharmacology Unit (MCPU) for maximum efficiency in conducting early phase clinical development projects.

**Medpace Bioanalytical Laboratories (MBL)**

Medpace Bioanalytical Laboratories is led by an executive management team and dedicated PhD and masters-level scientists averaging 10-20 years of pharmaceutical and bioanalytical study experience. Medpace Bioanalytical Laboratories focus on providing accurate, high-quality results in a timely, secure, and cost-effective manner. Our experts work in collaboration with the medical, regulatory, and imaging experts at Medpace to partner with your team to transfer, develop, validate methods, and ensure fast turnaround of analyses.

Medpace Bioanalytical Laboratories is a leading provider of bioanalytical services in all stages of drug development – from discovery to post-marketing.

**Breadth of Capabilities:**

- Method development, feasibility, and validation
- Drug discovery
- Nonclinical toxicokinetic (TK) studies
- Pre-clinical and clinical sample analysis
- Pharmacokinetic (PK) screening
- Clinical PK / bioavailability studies
- Bioequivalency studies
- Bioavailability studies
- Dose-escalating studies, with analysis and reporting capabilities for thousands of samples within short timeframes
- Drug interaction studies
- Drug-Drug interaction studies
- Clinical study-compliance samples

Leveraging state-of-the-art instrumentation, techniques, and facilities, our team of experts has experience in a broad range of analytical support. Working in a current Good Laboratory Practice (cGLP) compliant setting, Medpace Bioanalytical Laboratories team members provide method transfer, development, validation and analysis of preclinical and clinical biological samples. We have extensive expertise in developing sensitive methods utilizing a number of bioanalytical technologies; LC-MS / MS, ELISA, ECL or qPCR assay. We have used these techniques to quantitate multiple-analytes, metabolites, prodrugs, and light- and temperature-sensitive compounds and we routinely establish and validate analytical methods in human and non-human species (including mice, rats, rabbits, dogs, and monkeys) in a variety of biological matrices.

#### Areas of Bioanalytical Expertise Include:

- Advanced, mass spectrometry technologies for bioanalytical analysis
- Ligand-binding assays for pharmacokinetics (PK) and immunogenicity assays
- qPCR for nucleic acid drug pharmacokinetics (PK) or pharmacodynamics (PD)
- All bioanalytical aspects for small and large drug molecules according to cGLP, OECD, and ICH compliances
- Rapid transition of methods between species and matrices while providing performance according to FDA, OECD, and ICH guidelines

#### Advanced equipment, instrumentation, and software:

- AB Sciex 6500 high resolution Q Trap LC-MS/MS systems
- AB Sciex 5600 high resolution LC-MS/MS systems
- API-5500 Sciex Q trap LC-MS / MS Systems
- API-4000 Sciex LC-MS / MS Systems
- UFLC Shimadzu LFLC/HPLC LC-30XR Systems (19,000 PSI)
- HPLC Shimadzu UFLC / LC-20 Systems
- ELISA instruments with Absorbance, Fluorescence, Luminescence
- MSD Sector Imager 2400 (Multiplex)
- Eppendorf qPCR (Realplex)
- GC-MS
- Watson LIMS System v7.3
- Automated sample preparation and TomTech Quadra SPE 4
- Complete services for labeling, shipping, and storing biological samples

#### Our spacious 30,000 sq. ft. facility features:

- Refrigerated storage (4°C)
- Low temperature storage (-20°C to -80°C)
- Emergency back-up electrical and heating services
- Video security
- Onsite archive facility
- Bar coding system

#### Contact Information:

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