

**COMPLETE BIOANALYTICAL SERVICES  
IN ALL STAGES OF DRUG DEVELOPMENT**

The highest quality experts, instrumentation, techniques, and facilities to deliver custom drug development solutions from discovery to post-marketing.



# MEDPACE BIOANALYTICAL LABORATORIES

**MEDPACE**

THE ADVANTAGE OF FOCUS

# MEDPACE BIOANALYTICAL LABORATORIES



## A dedicated partner who can engage quickly

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.

## From discovery to post-marketing

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

- 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

## Only Medpace delivers this level of expertise

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 (cGMP) 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 for LC-MS / MS – qualifying multi-analysis, 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. Our discovery team regularly performs fast PK, bioavailability, and early toxicology studies.

The Medpace Quality Assurance team provides ongoing guidance and regulatory training to the Bioanalytical Laboratories team, ensuring that validations are performed in accordance with OECD and FDA guidelines.

Areas of bioanalytical expertise include:

- Advanced, mass spectrometry technologies for bioanalytical analysis
- All bioanalytical aspects for small and large drug molecules according to cGMP, OECD, and ICH compliances
- Rapid transition of methods between species and matrices while providing performance according to FDA, OECD, and ICH guidelines

## State-of-the-art instrumentation and facilities

Medpace Bioanalytical Laboratories feature the following advanced equipment, instrumentation, and software:

- API-4000 Sciex LC-MS / MS Systems
- API-5500 Sciex Q trap LC-MS / MS Systems
- HPLC Shimadzu UFLC / LC-20 Systems
- Watson LIMS System
- Automated sample preparation

We also provide complete services for labeling, shipping, and storing biological samples. Our spacious 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

## The Medpace difference

Medpace is a global, research-based drug development company led by top therapeutic and regulatory experts who are driven to further the advancement of pharmaceutical agents for use in cardiology, metabolism, and oncology. Medpace has assembled the industry's most experienced and therapeutically-focused team to execute at all levels of our operations, providing complete and seamless drug development services.

Through specialized regulatory expertise and therapeutically-focused clinical operations, Medpace creates strategic partnerships with pharmaceutical and biotechnology companies to provide the most efficient and cost-effective path to drug development – from program planning and execution to product approval. With clinical trial experience in over 40 countries, Medpace has the global reach and capability to successfully conduct studies and navigate regulatory requirements worldwide.

## Medpace group of companies

**Medpace**

**Imagepace**

**Medpace Bioanalytical Laboratories**

**Medpace Clinical Pharmacology**

**Medpace Reference Laboratories**