



Bioanalysis – Discovery, Nonclinical, and Clinical

Services

- Synthetic chemistry
- Method development and validation
- Sample collection: a 3Rs approach
- Non-GLP discovery bioanalysis
- Nonclinical bioanalysis
- Clinical bioanalysis

Comprehensive bioanalytical support is key at every stage of development, from discovery to nonclinical studies, as well as all phases of clinical development. According to a Nice Insight Survey¹, outsourcing has increased from 20% to 40% in the past five years. However, the top issue raised with outsourcing is that using multiple vendors and contracts brings a lack of integration that doesn't allow data to be brought together easily. We have the solution.

At Charles River, our experienced scientists develop, validate, and apply quantitative bioanalytical methods for compounds ranging from small molecules to larger proteins, providing our clients with the exact bioanalytical support they need to quickly and efficiently accelerate their products from target ID to clinical bioanalysis. Our laboratories have the latest instrumentation to measure drug, metabolite, and endogenous concentrations in biological matrices, such as plasma, serum, cerebrospinal fluid (CSF), urine, and tissues, using a wide range of techniques and technology platforms.

This variety of advanced equipment ensures that we have the capacity to support clients with rapid lead-in and turnaround times in order to meet critical deadlines. This brings a number of benefits, the most significant being efficiencies in the collation and reporting of data.

EVERY STEP OF THE WAY



Sample Platforms

- LC/MS, HRMS
- LC-MS/MS
- GC
- ICP
- Mass spectrometry
- Ligand binding
- Immunoassays
- QPCR
- Cell based assays

Synthetic Chemistry and Method Development

To assist in quantitative bioanalysis, our chemical synthesis group can produce non-labeled or stable isotope-labeled compounds, such as deuterated or carbon-13 analogues, for use as internal standards. We can also assist with metabolite identification, profiling, and synthesis. Dedicated method development teams are able to rapidly evaluate and develop assays to support nonclinical and clinical programs.

Sample Collection: a 3Rs Approach

The microsampling technique allows for discovery and nonclinical studies to incorporate a 3Rs approach to study design. Charles River has developed a vast amount of microsampling experience both from the in life and the bioanalytical aspects of supporting drug development. We have supported over 230 studies globally and validated over 65 methodologies all using capillary microsampling to support regulatory facing studies. We also have experience supporting the use of a variety of other microsampling techniques such as dried blood spots, Aquacap (TM Drummond), and Microvettes (TM Sarstedt).

Discovery Bioanalysis (Non-GLP)

Charles River's dedicated discovery groups excel in conducting discovery studies ranging from rapid high-throughput pharmacokinetic (PK) screening and bioanalysis to lead optimization. Our commitment to providing our clients with the data they need has resulted in a range of specific discovery bioanalytical offerings. These research-grade assays (RGAs) have been developed and optimized to provide defined quality and rapid turnaround of analytical data for numerous discovery programs.

Nonclinical Bioanalysis (GLP)

Our experienced scientists develop, validate, and apply quantitative methods to measure drug and metabolite concentrations for samples in plasma, serum, cerebrospinal fluid (CSF), urine, and tissues. Our comprehensive services can be performed on both small and large molecules, including antibody-drug conjugates, biosimilars, monoclonal antibodies, oligonucleotides, peptides, proteins, and vaccines. Scientists in our eight safety assessment laboratories located throughout North America, the United Kingdom, and mainland Europe analyze over 250,000 nonclinical samples per year.

Rapid access and review of data allows our clients to quickly and efficiently make go-no go decisions. The mycharlesriverSM portal provides secure access to data from discovery, development, and testing programs. The propriety portal features a customizable, easy-to-use dashboard where clients can review important study information such as calendars, contacts, forms, and reports.

Clinical Bioanalysis (GLP)

With well established experience in sample management and kit assembly for Phase I through III clinical trials worldwide, we produce over 1,300 sample kits per month. Additional data management support is provided by mycharlesriverSM, our global data portal for customizable solutions and secure trial tracking. In many cases, our scientists are involved at the start of the nonclinical program and stay on through subsequent testing, collaborating as part of the clinical study team. This approach results in robust and reliable methods for clinical sample analysis, which, when combined with data management, enables Charles River to provide high-quality on-time clinical data to support drug approval.

1. H. Hammeke K. Can CROs Help Reduce The Expense Of Clinical Trials [Internet]. [cited 2017 Jun 13]. Available from: <https://www.clinicalleader.com/doc/can-cros-help-reduce-the-expense-of-clinical-trials-0001>