charles river

Laboratory Sciences

Quality, scientific integrity, cost-effectiveness and regulatory compliance are essential considerations when selecting an outsourcing partner. Charles River is adept at balancing these key values within the most stringent of time frames to deliver comprehensive laboratory services from early screening through preclinical and clinical support.

With multiple facilities in North America, the United Kingdom and mainland Europe, we provide clients with the consistent application of laboratory procedures, regardless of study location. Whether clients wish to outsource the entirety of their laboratory work, or simply need to supplement their own in-house capabilities, our global facilities provide the full-service resources to meet their requirements. We believe in remaining at the forefront of laboratory technology and are quick to evaluate and invest in new technologies as they become available.

Services:

- Bioanalysis
- Drug metabolism and pharmacokinetics
- Immunology
- Molecular biology
- Biomarkers
- Formulation development, pharmacy, and analytical chemistry
- Clinical laboratory support
- Genetic toxicology
- *In vitro* toxicology

EVERY STEP OF THE WAY

Bioanalysis

Charles River provides routine and specialized bioanalytical services supporting discovery through preclinical and clinical programs (phase I-IV). Our scientists excel at development and validation of quantitative bioanalytical assays from first principles or by method transfer from a client's laboratory. Support spans all stages of development, beginning with non-GLP high-throughput pharmacokinetic (PK) analysis that offers fast turnaround to assist lead candidate selection. This early data aids the design or selection of validated assays that are in full compliance with GLP/Good Clinical Practice (GCP) and other internationally recognized regulatory guidelines. Our comprehensive services can be performed on small molecules and large molecules, including antibody-drug conjugates, biosimilars, monoclonal antibodies, oligonucleotides, peptides, proteins and vaccines.

Drug Metabolism and Pharmacokinetics

We provide responsive service and timely data for a full range of absorption, distribution, metabolism and excretion (ADME) studies covering a broad spectrum of both non-GLP screening and GLP studies employing cold or radioactively labelled test material. As a true end-to-end CRO, we can support clients in lead candidate selection, preclinical testing and clinical development (Phase I-III) programs with both *in vitro* and *in vivo* services.

Immunology

Our comprehensive immunology, immunotoxicology and immunogenicity testing supports our clients' discovery, preclinical and clinical programs for drugs and biologics. Our scientific, technical and support staff work together in dedicated immunology laboratories to conduct non-GLP and GLP/GCP immunotoxicology assessments. We conduct full method development/optimization, followed by validation and high-throughput sample analyses, which are performed in accordance with GLP/GCP regulations.

Molecular Biology

Charles River performs a comprehensive array of genomics-based assays to support all phases of drug development, from discovery to preclinical studies through clinical trials. Our nucleic acid extraction procedures are optimized for high purity and high yield from a variety of tissues, body fluids, cells in culture or any biological sample. We collaborate with clients to transfer and optimize assays and can guide assay development and validation, sample processing, and data analysis and interpretation.

Biomarkers

We provide a wide selection of qualified non-GLP and validated preclinical and clinical biomarker assays across several therapeutic areas, including respiratory disease, oncology, CNS, and metabolic diseases. Our scientists work with multiple singleplex and multiplex immunoassay platforms as well as support biomarkers for imaging, physiological and functional assessments, and behavioral assessments. Capabilities span the identification and validation of biomarkers and the development of quantitative assays in primary cells and disease tissue, pharmacodynamic and disease models, and as efficacy and translational medicine markers in the clinic.

Formulation Development, Pharmacy and Analytical Chemistry

Charles River's formulation and analytical chemists support the development of our clients' industrial chemicals, polymers and pharmaceutical compounds with a full range of services, from preformulation investigations and vehicle screening and selection to assay development and validation. Using the latest instrumentation and our technical expertise, we deliver the bioavailable, stable and scalable compounds that are critical for the success of nonclinical studies. In addition, our staff can develop analytical methodologies that suit the needs of any study.

Clinical Laboratory Support

We provide clinical support of bioanalysis, immunology, molecular biology, formulations, DMPK, and biomarkers for clinical programs. With over 40 years of experience in sample management and kit assembly for Phase I through III worldwide clinical trials, our kits are specifically designed to optimize collection, storage and shipment of clinical samples.

Genetic Toxicology

Genetic toxicology helps discern the possibility of heritable mutations, developmental defects, cancer initiation, aging and other long-term adverse genetic effects. These studies are conducted early in the safety testing program of pharmaceuticals, medical devices, chemicals, agrochemicals, food additives, etc. We conduct a full range of genetic toxicology studies, from early screening studies to mammalian cell and *in vivo* assays with multiple integrated endpoints.

In Vitro Services

Charles River has been leading the way in the development, validation and acceptance of various animal-free models from early screening through preclinical and clinical support. Many of our assays are direct replacements for tests or screenings done on animals. Testing is available for individual ingredients, mixtures or final products. Our range of model systems results in multiple toxicology endpoints for better decision making at the lead optimization stage of testing, which provides endpoints for registration dossiers under REACH and supports other regulatory requirements.

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