charles river

Large Molecule Bioanalysis

Peptides, monoclonal antibodies, multispecific antibodies, antibody drug conjugates, biosimilars, traditional and next generation oligonucleotides – Charles River scientists have been global leaders in large molecule bioanalysis throughout this rapidly growing and evolving field.

From *de novo* assay development to transfer of established methods from your laboratory to formal validation and on to sample analysis, Charles River scientists in our North American and European laboratories have the breadth of scientific expertise necessary to deliver results meeting regulatory compliance applicable to your study and region of the world. Studies are supported with a validated Watson™ Laboratory Information Management System (LIMS) bringing a number of benefits the most significant being efficiencies in the collation and reporting of data.

Whether you need assistance with drug development, preclinical safety testing or clinical sample analysis, Charles River has the skills and experience to support all stages of your drug development program.

Large molecule bioanalysis is not an independent discipline; our scientists work closely with our immunogenicity, pharmacokinetic and statistical specialists to deliver the pertinent solutions and interpretation applicable to *your* molecule and *your* study.

With experience obtained over several decades, our scientists across the globe work in collaboration with you as one team, providing solutions tailored to your molecule and program.

Benefits of the Charles River Approach

Dedicated method development teams are able to rapidly evaluate and develop assays for you, and all of our facilities provide exceptional quality, high sample throughput and on time reporting. Our firsthand knowledge in the development of a wide range of compounds and our experience across the drug development continuum helps you create an efficient, successful program from discovery through clinical pharmacology. As one of the largest service providers in the industry, Charles River offers a broad technical portfolio of essential laboratory services around the world, bringing responsiveness and innovation to the pharmaceutical, biotechnology and health care industries.

Services

- Method feasibility and development
- Assay transfer from your own laboratory
- Method qualification
- Method validation following current regulatory guidance and applicable GLPs
- Preclinical sample analysis following applicable GLPs
- Clinical sample analysis
- Clinical sample management

Assay technologies and expertise

- Ligand binding assays, including conventional ELISA and MSD® platforms
- Automated ELISA systems
- Radioimmunoassay
- Oligonucleotide hybridization assays
- LC-MS/MS where applicable
- Analysis in plasma, serum, tissue and other biological matrices
- Low interference assays from target or antibodies

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