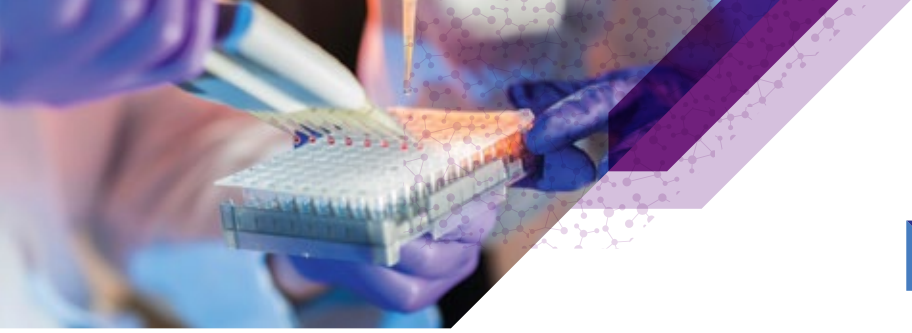

Q² Solutions®

Biotherapeutic Immunoassay Services for the Development and Validation of Ligand-Binding Assays

Immunoassays enable the sensitive and specific measurement of analytes in complex biologic matrices and thus play a central role in drug discovery and development. We are well versed in what it takes to develop and validate an immunoassay in the regulated bioanalytical setting through our deep understanding of the science, statistical analysis demands and experience in the complex regulatory landscape that exists today. These attributes, coupled with our comprehensive project management and the available capacity to support high-throughput platforms and complex methods in a compliant manner, position us well to service all your testing needs.

Since 2007, Q² Solutions has provided comprehensive support for developing and validating robust bioanalytical ligand binding immunoassay methods to support biotherapeutic studies at each step of the drug development pipeline. From pharmacokinetic studies and immunogenicity assessments to biomarkers, Q² Solutions has established a proven track record in regulated bioanalysis. Whether you are considering pre-clinical studies or planning a Phase III clinical trial, we can help you design tailored solutions that will meet your project's needs.

Q² Solutions offers a full range of services to support the development and validation of ligand-binding assays, including:

Project Management

Our Project Managers act as the principal points of contact to ensure that expectations, including timelines and cost, are met. All Q² Solutions Project Managers are scientists with hands-on experience in bioanalytical methodologies, bringing an average of nine years of industry experience to the table. Project Managers play an active role in analyzing study data, communicating results and making recommendations during formal weekly updates. Our Project Managers will serve as trusted partners in decision making to help your project run smoothly and efficiently.

Method Development

Q² Solutions leverages more than ten years of regulated large-molecule bioanalytical experience. We develop and validate robust bioanalytical methods to support PK concentration, immunogenicity (ADA and Nab) and biomarkers for novel agents and biosimilars.

With an average of 15 years of industry experience, our method development team can help you determine the appropriate immunogenicity assay formats to meet the drug tolerance needs of your bioanalytical project. All methods are designed with an aim to facilitate proper and efficient transition to validation studies.

Method Validation

Our production and method development teams work closely together to ensure a smooth transition from method development to method validation. Prior to initiating validation, a comprehensive pre-validation checklist of experiments is performed to ensure the analytical method is rugged, reproducible, and meets all regulatory standards. The lab also provides in-house cut point statistical analysis and characterization of critical reagents. Q² Solutions takes a proactive approach to adapt to the latest industry and regulatory best practices, thus ensuring that your project will be poised to meet scientific and regulatory requirements.

Turning Hope ***Into Help***

Sample Analysis

Q² Solutions' principal immunoassay laboratory is housed in a 20,000 square foot facility in Marietta, GA that is co-located with our central laboratory flow cytometry facility, cell culture laboratory, and translational sciences laboratory. With the critical mass to meet your study needs and MSD, ELISA, FL/CL, and Luminex platforms, our large molecule bioanalysis facility can carry out high-throughput studies while meeting aggressive timelines. Q² Solutions also supports global pharmacokinetic studies and biomarker analysis through dedicated space within our Central Laboratory facility in Beijing, China. All processes and SOPs at this GLP- and CFDA-compliant facility are harmonized with the Marietta site to ensure consistent delivery for global studies.

>1 MILLION
bioanalytical and ADME samples analyzed yearly

98%
of reports delivered on time

Sample Management

Q² Solutions has extensive experience in handling large volumes of samples on accelerated timelines. From initial receipt and assessment through final disposition, we maintain a chain of custody for all client compounds and study samples. All client-related inventory is managed under a set of rigorous SOPs that include quality control for critical reagents, metrology, and raw and processed data.

Medical Writing Support

Sample analysis and validation reports are prepared by our in-house medical writing team, which includes Ph.D.-level scientists with statistical analysis experience. All Q² Solutions reports comply with bioanalytical regulatory guidelines and undergo three layers of review. Draft reports are typically ready for sponsor review in 2-5 weeks following completion of data QC review.

26+ YEARS
of regulated and discovery bioanalytical experience

Q² Solutions has a proven track record for developing and transferring routine and complex bioanalytical methods. Our focus on quality and our global industry-leading expertise and resources can support a wide range of large-molecule immunoassay studies. Contact us today to discuss how our experienced bioanalytical team can help you develop and validate your immunoassay in a timely and regulatory-compliant manner.

Contact us

Toll free: +1 855.277.9929
Direct: +1 919.998.7000
International: +44 (0) 1506 814000
Website: www.Q2LabSolutions.com

Q² Solutions®