Q² Solutions®

Assay Development for Large-Scale Clinical Studies

Taking a candidate drug to market – and to the patients who will benefit from it – requires supporting data from high-volume, regulated clinical studies. From sample receipt to final reporting, Q² Solutions understands the importance of delivering qualified clinical sample data throughout all stages of the drug development cycle.

Q² Solutions' bioanalytical experts can partner with you to develop assays that incorporate state-of-the-art instrumentation, rigorous quality control, and a logistics infrastructure to support large-scale, international studies.

Q² Solutions can support your large-scale clinical projects by leveraging:

Expertise in Developing Assays for Human Samples. Q² Solutions has earned a reputation for excellence in method development through our experience with assaying human samples. Transitioning from animal studies to human subjects requires assays that can measure novel metabolites and accommodate low-level dosing studies. Q² Solutions will work with you to develop automated small molecule LC/MS assays, large molecule ligand binding assays, and large-molecule hybrid-LC/MS assays including high resolution mass spectrometry, to support all phases of the clinical trial process.

An End-to-End Assay Development Process. Recognizing that a clinical assay must be reliable over a period of years, Q² Solutions has implemented a rigorous procedure to ensure quality and reduce risk. Prior to validation, each assay undergoes a formal pre-qualification process in which Q² Solutions scientists review preliminary data and assess modifications necessary to support validation.

Project Managers with Scientific Expertise. All Q² Solutions Project Managers are scientists with hands-on experience in analytical methodologies. Our Managers understand the science behind the assays, verifying data quality and assuring that assays run smoothly for the duration of the project. Through weekly or bi-weekly updates, our Project Managers will address concerns or questions as they arise and serve as active collaborators in decision-making.

>1 MILLION
bioanalytical and ADME tests performed yearly

A Global Presence to Support International Studies. Q² Solutions combines local expertise with a global logistics network to support sample processing for international clinical studies. With facilities in the United States and China, Q² Solutions complies with global bioanalytical regulatory guidances. Q² Solutions is certified by ANVISA, the Brazilian health regulatory agency.

Flexibility with Transparency. All assays carried out at Q² Solutions facilities adhere to a common set of SOPs, thereby assuring consistent data quality. Bioanalytical and clinical Project Managers from different internal teams communicate regularly to resolve sample processing issues in a timely and transparent manner. Q² Solutions bioanalytical laboratories integrate with central facilities, offering a flexibility to adapt to shifting analytical demands and customer timelines.

Turning Hope ***Into Help***

Putting Q² Solutions Capabilities into Practice: A Case Study

Q² Solutions provided bioanalytical support for two randomized, double-blind, Phase III studies to assess the long-term safety and efficacy of various dosing regimens of a novel new drug and a comparator drug in targeted patient population groups. Over a four-year period, Q² Solutions assayed the pharmacokinetic profile of the compound and its major metabolite in plasma. Collectively, these studies required the analysis of over 50,300 samples (including placebos) from more than 29,000 subjects. For the larger study, samples were provided by nearly 1,400 centers located in 46 countries. A final bioanalytical report of over 8,000 pages was written in five weeks to meet an aggressive regulatory submission date. Results from these multi-institutional studies ultimately supported the U.S. Food and Drug Administration's approval of the drug.

Regulated & discovery bioanalytical experience

>135 unique assays performed in Ithaca in 2019. 25 unique assays in Marietta and 25 in Beijing

Translating a large-scale, long-term study into a successful outcome requires reliable, qualified measurements at a clinical scale. Q² Solutions' bioanalytical experts can help you design and carry out validated assays that will support all stages of your clinical study. To learn more, call us today or visit us at **www.Q2LabSolutions.com**.

Contact us

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