Q² Solutions®

Bioanalytical & ADME Laboratory Services

Q² Solutions offers global industry-leading expertise and resources to help support high quality delivery of routine and complex bioanalytical and ADME projects for our customers

Accelerate and enhance your discovery, preclinical and clinical programs

As increasing regulatory and scientific complexities threaten R&D productivity, you need a bioanalytical and ADME partner who can truly enhance the drug development process.

Q² Solutions helps our customers *improve human health* through innovation that transforms science and data into *actionable medical insights*. Q² Solutions delivers on this promise by offering tailored solutions, delivery excellence and the expertise to help you shape better outcomes for your clinical development programs.

Actionable Insights for **Better Health™**

Q² Solutions can help you with a full range of ADME and bioanalytical services from high-throughput ADME screening to immunogenicity testing.

Tailored bioanalytical & ADME solutions

From 20+ years of experience we understand the unique challenges faced by our customers today. In order to get your product to market you need a trusted bioanalytical and ADME partner who can deliver quality results on time and on budget. Our tailored solutions and extensive capabilities ensure you get the highest quality data you need when you need it.

Liquid chromatography–mass spectrometry (LC/MS) services for the quantitative determination of small molecule, peptide and macromolecule therapeutics in support of pharmacokinetic (PK) studies.

Immunoassay services – Quantitative determination of large molecule therapeutics using ligand binding technologies in support of pharmacokinetic (PK) studies. Immunogenicity assessments for pre-clinical and clinical studies including tiered based approaches, neutralizing assays and isotyping assays.

Fit-for-purpose biomarker services – Quantitative determination of discovery, pre-clinical and clinical biomarkers using LC/MS, Immunoaffinity-LC/MS and Immunoassay technologies in GLP-compliant facilities.

In vitro ADME assays and metabolite identification services – Permeability, metabolic stability, metabolite identification (cold & radiolabeled), and in vitro drug-drug interaction risk assessment, ranging from highly automated discovery screening platforms to definitive development studies that enable regulatory submission.

Advanced techniques to deliver new insights for our customers. We are one of the few bioanalytical laboratories successfully employing immunocapture, multidimensional (up to 3-D) liquid chromatography (LC) and high-resolution mass spectrometry (HRMS) for biological analyte LC/MS quantitation. We have an industry leading reputation in dried-blood spot (DBS) and dried-plasma spot (DPS) microsampling, and are one of the few service labs with experience in utilizing the HμREL® co-culture model to predict clearance and assess metabolic profiles of low turnover compounds.

Custom deliverables and processes – We excel at employing innovative processes and finding custom solutions for our customers including scheduling flexibility and tailored project management support based on your project's specific requirements. We know the importance of your deadlines and are willing to commit resources to meet your goals and timelines so you can keep your product on target.

Delivery excellence

Q^2 Solutions operates one of the world's largest and most respected bioanalytical and ADME laboratories. Through quality, capacity and experienced staff, we deliver excellence in every study we conduct.

Quality record – We put quality first throughout the entire process from method development to final report delivery so you have confidence in the results. Rigorous scientific and quality assurance reviews help to ensure the validity of reported data. We also use quality management systems and eSOP technologies for greater visibility and quality control. Our laboratories have a favorable regulatory inspection record including GLP inspections from clients as well as U.S., European and Brazilian regulatory agencies. The result is reliable, high-quality data for better decision-making, faster, more efficient drug development, and quality regulatory submissions.

On-time delivery record – We have a proven track record for timely delivery, and over the past year we have a 97% on-time delivery record for bioanalytical reports, meaning you get the data you need, when you need it.

Capacity and fast turnaround – We harness the scale and resources of one of the largest bioanalytical lab networks in the world to support your sample processing needs for large or small studies.

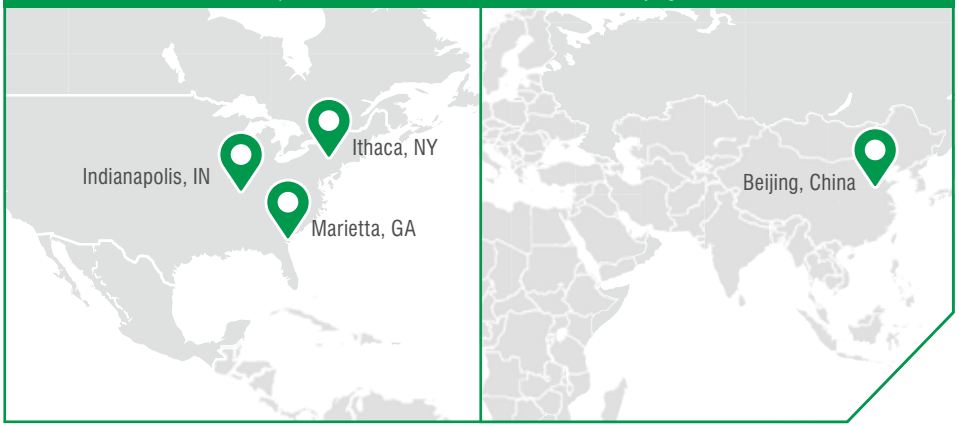
97%
reports on-time record for **bioanalytical reports**

98%
reports on-time record for **ADME reports**

>65	>550,000	+35	9.6
LC/MS systems globally	in vitro screening samples analyzed in the past year	assays using high-resolution mass spectrometry (HRMS)	quality rating by customers (scale of 1-10)

Global footprint – We serve many of the largest pharmaceutical, specialty pharmaceutical and biotechnology companies in North America, South America, Europe and Asia with scalable expertise and innovative solutions.

We have a broad network of bioanalytical and ADME laboratories, with locations in Indianapolis, IN; Ithaca, NY; Marietta, GA; and Beijing, China.



2 WEEKS
standard turnaround on **QC data** (72-hour and 48-hour turnaround availability by request)

Indianapolis, IN, USA

- Home to our Center of Excellence for automated in vitro ADME screening, discovery LC-MS/MS bioanalytical, in vitro metabolism, and metabolite identification capabilities
- Industry-experienced scientists and 22,000 square feet of lab space

Ithaca, NY, USA

- GLP compliant bioanalytical liquid chromatography mass spectrometry (LC/MS) laboratory
- LC/MS biomarker assays in support of PK/PD studies
- HRMS, Nano-flow chromatography and Immunoanalytical/LC-MS hybrid assays
- TK and PK studies

Marietta, GA, USA

- Home to our Immunoassay Bioanalytical (PK and immunogenicity) capabilities
- GLP compliant discovery bioanalytical/ligand binding assays – biologics and biosimilars
- Neutralizing immunogenicity cell-based assays
- Exploratory biomarkers

Beijing, China

- GLP compliant bioanalytical LC/MS laboratory
- CAP certified for LC/MS biomarker assays in support of PK/PD studies
- Immunoassay (PK and immunogenicity) capabilities

Project management – Each study is assigned a client-focused Project Manager who will be your direct contact and will collaborate with your scientists to fully leverage the experience available. Our Project Managers are experienced scientists who focus on scientific excellence, regulatory compliance and customer needs. Therefore, you can be confident that we are focused on completing your study to your specifications and within your timeline. Clients experience superior service and results during routine as well as non-routine projects. We have a flexible approach to scheduling and the ability to provide rapid turnaround of data.

Integration with parent organizations – From shipping expenses to establishing harmonized procedures between Phase I clinics and our labs, we effectively leverage systems and assets from IQVIA and Quest Diagnostics to drive optimized delivery of your project. Together with global clinical experts, and Q² Solutions' central labs network, we offer a one-source, streamlined laboratory solution for testing across the development spectrum, throughout the world.

Value for price – Delivering services right the first time reduces the need for expensive revisions and lost time to market. At Q² Solutions we have outstanding project management and scientific professionals supported by quality processes and technology that help us deliver your project on time and on budget. Over the past year we have a 97% reports on-time record for bioanalytical reports and 98% reports on-time record for ADME reports.

Shaping outcomes

Our highly trained scientists utilize a range of leading-edge technology, automation and state-of-the-art techniques to shape better outcomes for your clinical development programs.

Method development expertise – Our process includes an upfront feasibility assessment, as well as bringing best practices and previous experience to the project. Our focus is to develop a robust and rugged method that has a high success rate in validation and sample analysis with minimal failed runs. Our method and assay development work focuses on delivering robust and rugged assays, with a high validation success rate, with minimal failed runs in production. Finally our internal method validation team conducts a thorough review of the data and assay to Q² Solutions or client specified criteria.

World-recognized scientific leaders – Q² Solutions offers industry-leading expertise and resources in support of routine and challenging small and large molecule bioanalytical, immunogenicity and ADME programs. Our leaders are very active in the bioanalysis and ADME communities and strive to bring the latest innovative approaches and solutions to your study.

High science and pharma expertise – We know the science, but also understand the pharma industry and how to effectively deliver sound results that matter to you and your organization.

Consulting and guidance to help your organization navigate the bioanalytical and ADME environment – from understanding effective implementation of new technology to current regulatory requirements so you achieve optimized outcomes.

Let's improve human health together

Contact us to learn more about Q² Solutions and how we can put our experience and expertise to work for you by providing you with actionable insights for better health.

100+
scientific publications and presentations in past 5 years

Dedicated MD scientists with 118 YEARS' collective bioanalytical experience with the company

Contact us

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Q² Solutions®