QACAL
PROFESSIONAL SERVICES

Clinical Pharmacology and Bioanalysis

The Foundational Milestone of Product Development

The collection of first-in-human data is a critical component in the journey from lab to life.

The dedicated Clinical Pharmacology and Bioanalysis team at QA CAL has been tailoring solutions for navigating this challenging phase of clinical development.

QA CAL Provides Global Solutions for Your Clinical Pharmacology and Bioanalysis Needs

- Broad expertise in various study designs in all therapeutic areas in both healthy volunteers and patients
- Experience with a wide range of dosage forms to facilitate study and protocol development for efficient regulatory submissions
- Proficiency in conducting any Phase I to Phase IIa studies including:

first-in-human (FIH), single ascending dose/multiple ascending dose (SAD/MAD)
proof-of-concept
drug-drug interaction (DDI)
renal and hepatic impairment
thorough QT/QTc (TQT)
biosimilars
pharmacokinetics (PK)
505(b)(2) support services
ethnobridging
bioavailability, bioequivalence and food effect

- Robust experience with an array of investigational products (IPs), including those of biological origin, and with multiple delivery methods
- Access to diverse patients and special populations including obese (BMI >30) or elderly participants (65 years or older)

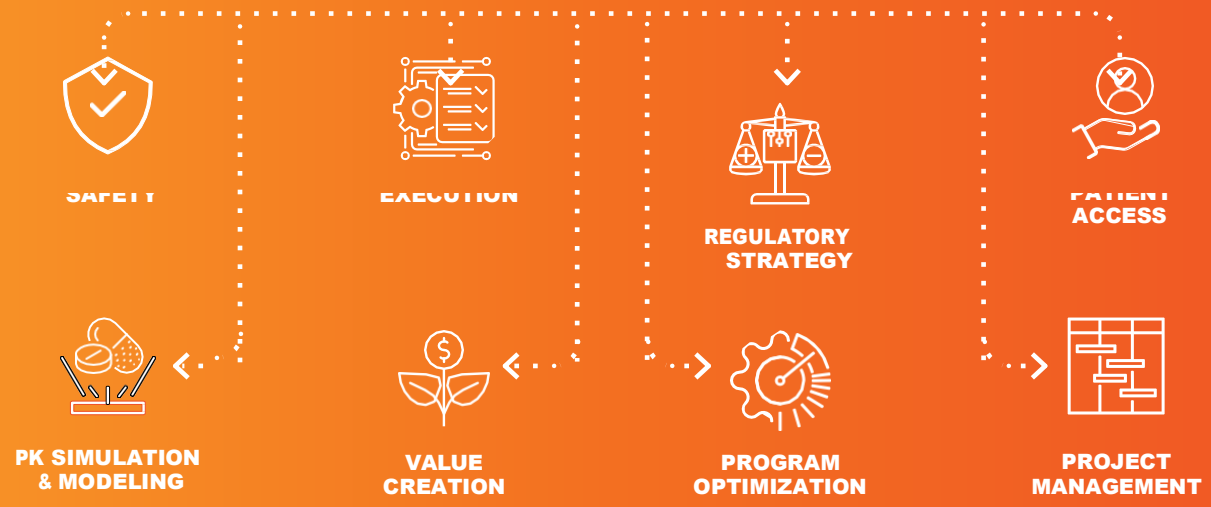
Specialized Expertise from QA CAL to Meet Any Challenge

In today's fast-paced drug development environment, data is produced at an exponential rate. Efficient extraction of knowledge from the data to support development is becoming a cornerstone of success, and our multi-faceted team delivers on these key areas:

- **Model-informed Drug Development**—specifically aimed at extracting knowledge from existing data, identifying knowledge gaps, and creating actionable insights.
- **Pharmacometrics**—purposefully built to derive and apply knowledge to address issues pertaining to product development questions, including informing trial designs, supporting evidence of effectiveness and safety, predicting study outcomes, and leveraging the totality of evidence to support drug applications to regulatory bodies.
- **Biometrics**—dedicated to Phase I studies, providing a full range of services including clinical pharmacology, data management, statistics, medical writing and regulatory consulting.
- **Bioanalytical Solutions**—a global team of 300+ employees at three sites (in the United States, Canada and Western Europe) offering the full spectrum of assay services (development, validation and analyses) for pharmacokinetics, immunogenicity and biomarker assays, making QA CAL a Top 3 global provider of bioanalytical services.

Focused Execution and Planning for What Comes Next

QA CAL provides an evolved, multi-disciplinary approach to Early Phase clinical development and offers these services to its customers:



Global Reach Tailored to Your Needs

The global reach of QA CAL, combined with its collaborative approach, offers full-scale support for the development of your product. In addition, we can leverage our therapeutic area experience to expand into other countries for Phase II and III studies as needed.

- QA CAL Phase I sites—expanded Quebec City (Canada) and Miami (USA) sites with newly improved beds, as well as bioanalytical labs in Princeton (USA), Quebec City (Canada) and Sophia-Antipolis (France).
- Flexibility and options for our customers—strategic collaborations with external Phase I units/sites with local resources in North America, Europe, Australia, New Zealand and APAC.
- Regulatory support and guidance—access to various global regulatory environments across APAC, EU/UK and North America.

> **“QA CAL has assembled an exceptional team of former senior- level FDA and EMA officials and other international regulatory and pharmaceutical experts within our Regulatory Consulting, Clinical Pharmacology and Bioanalysis teams.”**

The Unique QA CAL Collaboration Model

QA CAL has developed an unparalleled solution for studies requiring clinics outside our own facilities. We have successfully leveraged independent sites to enable us to provide the best geographical solution for your studies. We have developed strong collaborations with external Phase I units in North America, Europe, Australia and New Zealand, and have an established relationship model which allows for flexibility, commitment, options and early phase expertise for our clients. This collaboration motivates participation and engagement while incorporating experienced staff and facilities for effective study oversight and execution with quality.

Regulatory Consulting Within QA CAL Clinical Pharmacology and Bioanalysis

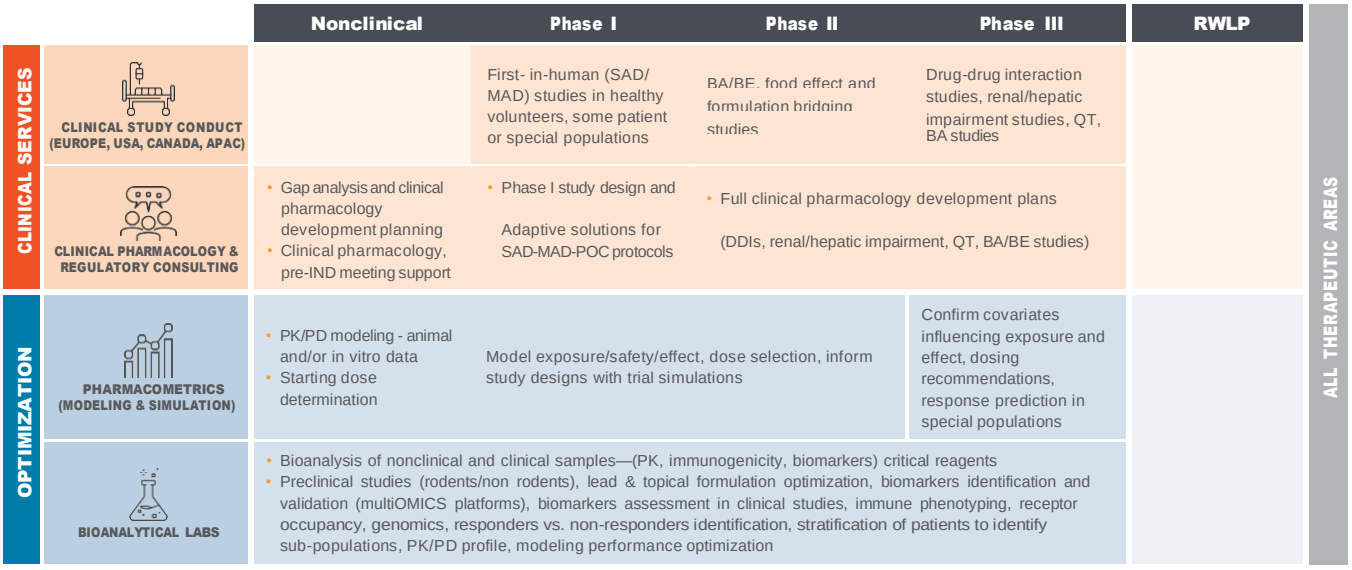
To help sponsors navigate the ever-changing regulatory environment, QA CAL has assembled an exceptional team of former senior- level FDA and EMA officials and other international regulatory and pharmaceutical experts within our Regulatory Consulting, Clinical Pharmacology and Bioanalysis teams. These experts provide comprehensive support services to help sponsors navigate the 505(b)(2)[1] regulatory pathway and help companies in the APAC navigate their challenging route to FDA approval.

Whether you are considering brand extensions, new indications, formulations, active ingredients, dosage forms or a combination of new entities, we have the strategic and scientific expertise to help you develop and introduce new and improved products and invigorate their brands.

Early Phase is More Than Phase I

QA CAL offers a breadth of services across the entire product development lifecycle. By providing a seamless development solution, we ensure that projects are executed at the highest-level quality, and the speed and transparency required to meet your goals.

Clinical Pharmacology and Bioanalysis Breadth of Services Across All Phases



Why QA CAL as Your Clinical Pharmacology and Bioanalysis Partner?

Beginning with the end in mind, QA CAL combines world-renowned clinical research, bioanalytical and commercialization capabilities, and innovative science, business and data technologies to make real advances possible. We recruit the right volunteers for each study with rapid enrollment while putting volunteer and patient safety and comfort first.

QA CAL has extensive experience in conducting various Early Phase and Clinical Pharmacology studies. We have ample bed space and the flexibility to run your trial at any of our Phase I facilities and maintain strong relationships with local Phase I clinics. This unique collaboration enables us to provide you with a small boutique feel, along with all the advantages of a large global product development company.

Want to Learn More?

info@qacal.in

About QA CAL

QA CAL is the only fully integrated biopharmaceutical solutions organization purpose-built to accelerate customer success. We lead with a product development mindset, strategically blending clinical development, medical affairs and commercial capabilities to address modern market realities.

Together we share insights, use the latest technologies and apply advanced business practices to speed our customers' delivery of important therapies to patients. We support a diverse, equitable and inclusive culture.

To learn more about how we are **Shortening the distance from lab to life®**, visit qacal.in.

Contact us

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