Fact Sheet

Small Molecule Bioanalytical and ADME Solutions

IQVIA Laboratories leads with science and offers tailored and comprehensive small molecule bioanalytical and ADME laboratory services. We combine scientific excellence, high-quality project management, and outstanding delivery with a quality record supporting regulatory-compliant data submissions integral to your drug development and approval programs.

Bioanalytical and ADME services – discovery through late phase

DISCOVERY (NON-GLP)	PRECLINICAL/ NONCLINICAL (GLP)	CLINICAL PHASE I	CLINICAL PHASE II-IV (LATE PHASE)
• High throughput ADME screening • Discovery and tiered bioanalysis • Metabolite identification and profiling • *In vitro* DDI	• *De novo* method development • GLP-compliant LC-MS analyses to support TK studies • Expertise from fit-for-purpose to BMV/GLP compliance	• *De novo* method development and transfers • SAD/MAD studies and rapid turnaround • PK support (bioequivalence/ bioavailability) studies • PD support of small molecule biomarkers	• Focus on automation and assay efficiency • Project and sample management experience • Supports multi-site and global clinical trials

Tailored bioanalytical and ADME solutions

Scientific excellence

With over 30 years of regulated bioanalytical experience, IQVIA Laboratories is one of the most respected bioanalytical and ADME laboratories continually driving innovation through scientific excellence and high-quality data. In addition to traditional blood plasma and serum assays, we have core experience with whole blood, urine, cerebrospinal fluid, tumor, ocular, skin, and other tissues. Across all therapeutic areas, including rare diseases, the scientists at IQVIA Laboratories are ready to partner with you to accelerate your drug discovery, preclinical, and clinical programs.

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Quality record

IQVIA Laboratories has global, industry-leading expertise to deliver high-quality results for routine and complex bioanalytical assays. Projects undergo rigorous scientific and quality assurance reviews to ensure compliance with internal and external study plans, standard operating procedures (SOPs), regulatory guidelines, and industry standards. Our laboratories have an outstanding regulatory inspection record that includes client-initiated inspections and U.S., European, and Brazilian regulatory agencies.

Project management

Our Project Management team has the bioanalytical experience, clinical trial expertise, and tools to deliver the communication and collaboration you need from a bioanalytical partner. This team includes an assigned project manager (PM), bioanalytical study lead (SL) and a data coordinator (DC). Each project has a dedicated PM who is committed to responsiveness and proactive communication for the duration of the study. The PM team provides a single point of contact for internal and external stakeholders (PM) and the SL has the scientific acumen to address project needs quickly and efficiently.

Delivery excellence

IQVIA Laboratories provides flexibility to adapt to shifting analytical demands and customer timelines. With a focus on responsiveness and deliverables, we have an impressive performance record of 95% on-time report deliveries. When projects require rapid turnaround times, particularly in support of SAD/MAD studies, our Project Management and Operational teams are leaders in ensuring data is delivered on time to meet project milestones.

Continuous investments in instrumentation, equipment and facilities

At IQVIA Laboratories, we constantly evaluate and upgrade equipment providing state-of-the-art instrumentation to anticipate market dynamics and our sponsors' needs. New instrumentation and cutting-edge methods continue to push the boundaries of bioanalytical assay sensitivity and throughput. While some needs may be met by new instruments, we are innovating our internal systems to provide more effective and efficient means of tracking real-time inventory through our Electronic Lab Notebook (ELN) system. Utilizing this system allows us to minimize study start up delays by leveraging our relationships with suppliers with on-time delivery of critical reagents and supplies. IQVIA Laboratories has fully integrated automation in our laboratory workflow by implementing Hamilton Microlab® STAR™ and Tecan® platforms to enable on-time delivery with large sample quantities. In addition, our ADME lab utilizes a compound tracking system providing time-saving and accurate retrieval of compounds to enable high throughput analysis.

Global presence with regional expertise

With bioanalytical labs in the United States and China, our team utilizes a harmonized approach to support our global clinical trials. To meet significant demands of our clients, IQVIA Laboratories also has the bioanalytical capabilities to support the largest pharmaceutical, specialty, and biotechnology companies around the globe. By leveraging the clinical trial expertise of IQVIA and coupled with the vast laboratory network of IQVIA Laboratories, we offer a comprehensive solution to support testing across the entire drug development continuum.

IQVIA LABORATORIES

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