Q² Solutions®

ADME Services from Q² Solutions

Accelerating your drug discovery, preclinical and clinical programs

As increasing regulatory and scientific complexities impact R&D productivity, you need an 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 shaping outcomes.

>175 PhDs and **>35** MDs

>750 discovery metabolite ID assays performed a year

Tailored solutions for your DMPK needs

Whether you need high-throughput ADME screens to optimize the properties of your drug candidates or you are looking to identify the enzymes responsible for metabolic clearance, we focus on execution of stage-appropriate studies by providing solutions to accelerate the development of your product.

Our solutions include a broad array of assays and services, including:

ADME Screening Services	• Solubility (turbidimetric) • Microsomal stability • Hepatocyte stability • P450 inhibition • Time-dependent inhibition (TDI)	• P450 reaction phenotyping • Permeability (MDCK, PAMPA) • Protein binding (plasma, microsomal or brain) • Plasma/S9 stability
Definitive In Vitro Assays	• Intrinsic clearance • Hepatocyte coculture models • P450 reversible inhibition & TDI • P450 induction, mRNA	• P450 reaction phenotyping • Glucuronidation clearance • Protein binding
Metabolite Profiling and Identification	• Discovery screening: In vitro & in vivo • Phase I metabolite scouting	• Metabolites in Safety Testing (MIST) assessments • Regulatory packages with radioprofiling

Turning Hope ***Into Help***

While our scientists routinely conduct industry-standard in vitro ADME assays, we are also continuously developing novel in vitro assays to address current metabolism issues and the evolving needs of our customers.

Current ADME Issue	**Non-P450 metabolism** *Including glucuronosyltransferase (UGT) and aldehyde oxidase (AO)-mediated metabolism*	**Slowly metabolized drugs**	**CYP3A5** *A polymorphic drug-metabolizing enzyme*	**Metabolite-in-Safety-Testing (MIST)**
Challenge	Phenotyping, species differences, and under-prediction of clearance	Intrinsic clearance and relevant metabolites unable to be predicted using conventional in vitro models with limited maximum incubation times	Assuming CYP3A4 is the predominant CYP3A enzyme contributing to metabolism may mask potential risk of clinical variability for PK or efficacy	Unforeseen safety issues and/or delays in the clinic due to disproportionate or unique human circulating metabolite
Solutions *to help better predict clinical outcomes*	We can design and execute in vitro studies to diagnose non-P450 pathways and better understand the drug-drug interaction and species-specific metabolism potential of your drug.	We have experience with hepatocyte co-culture models where incubations can proceed for up to 7 days to enable human clearance prediction and robust metabolite generation for low turnover drugs.	With the discovery of CYP3cide, a selective inactivator of CYP3A4, estimation of the CYP3A5 contribution to total CYP3A metabolism using individual CYP3A5*1*1 donor HLMs is possible.	We have the experience to confidently profile first-in-human plasma to enable assessment of MIST coverage needs.

Delivery excellence

Whether your target compounds are for neuroscience, infectious disease, inflammation or oncology, our scientists are ready to collaborate with you to accelerate your drug discovery, preclinical and clinical programs. Our scientific expertise coupled with frequent and collaborative communication is key to our mission to be a true partner in your development efforts. Our team understands the value of your product and fully appreciates the trust you place in us to deliver timely, quality results.

>750,000 in vitro screening samples analyzed in the past year

Q² Solutions utilizes the following instruments and technology to obtain the accurate and reliable data crucial to a successful regulatory submission and approval.

- Mass spectrometers:
  - AB SCIEX triple quadrupoles
  - Thermo Fisher Scientific Orbitrap™ and Q Exactive™
  - Waters Premier and SYNAPT® QTOFs
- Radioprofiling equipment:
  - PerkinElmer TopCount® and MicroBeta® counters
  - LabLogic βRAM5 and ARC radioflow detectors
- Automated in vitro sample preparation and handling equipment:
  - Tecan and Hamilton

Q² Solutions also has a highly automated laboratory to enable large scale ADME screening efforts using in-house or client-customized protocols, with rapid turnaround to co-optimize the ADME properties of your chemical platform alongside your potency and selectivity targets. This co-optimizing of ADME properties allows our customers to make important decisions about their potential compounds.

Shaping outcomes

What truly differentiates us from other ADME/DMPK service providers is the diversity in real-world pharma experience of our scientists and scientific leadership. More than half of our ADME team has previous clinical research or pharmaceutical industry experience. Our scientific leaders understand regulatory expectations having authored numerous regulatory reports and/or submission documents. From both a scientific and a regulatory standpoint, we have the experience and expertise to guide your drug discovery and development programs. By applying our best practices and scientific acumen we deliver confident decisions and outcomes for our customers.

Learn more about how we help our customers at
www.Q2LabSolutions.com/ADME

Contact us

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

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