Q² Solutions®

ADME services from Q² Solutions

Leading with science and 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 turns hope into help. Q² Solutions delivers on this promise by offering tailored solutions, delivering excellence and shaping outcomes.

25% of highly trained staff have PhDs

30+ years of experience

350 discovery metabolite ID assays performed

Tailored solutions for your DMPK needs

Whether you need high-throughput ADME screenings 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 consist of a broad array of assays and services, including:

ADME screening services	• Solubility (turbidimetric) • Microsomal stability • Hepatocyte stability • CYP inhibition/Time-dependent inhibition (TDI)	• P450 reaction phenotyping • Permeability (MDCK, PAMPA) • Protein binding (plasma, microsomal or brain) • Plasma/S9 stability
Definitive *in vitro* assays	• Human clearance predictions • CYP inhibition - reversible and TDI • CYP induction • CYP phenotyping • Non-P450 metabolism • Blood/plasma • HμREL clearance • Bundled services available in support of IND filing • P450, mRNA and activity	• Non CYP assays (AO and FMO) • P450 reaction phenotyping • Glucuronidation clearance • *In vitro* and clinical protein binding
Metabolite profiling and identification	• *In vitro/in vivo* metabolite profiling • Hepatocyte co-culture models (low-turnover) • Reactive metabolite trapping with GSH, CN, etc. • Quality/Quantity by HRMS stability indicating assay • Peptide mapping • ADC-payload DAR	• UGT inhibition • Exploratory metabolite profiling with "cold" TA » *In vitro* » *In vivo* (non-clinical) » *In vivo* (clinical) » Qualitative and ID • Radiolabeled metabolite profiling » *In vitro* and *in vivo* » Non-clinical and clinical • Custom design studies

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 more accurately 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 seven 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.

Delivering 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 collaborate 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.

Ability to screen >750
in vitro screening samples per 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:
- SCIEX triple quadrupoles and QTRAPs
- Thermo Fisher Scientific Q Exactive HF, Thermo Orbitrap Exploris™ 240 mass spectrometer with Nanoflow
- Waters SYNAPT® QTOFs

Radioprofiling equipment:
- PerkinElmer Microbeta and MicroBeta2® counters
- LabLogic βram5 radioflow detectors

Automated sample preparation and handling equipment:
- Tecan

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 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 submission documents. From both a scientific and 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.

Scan here to learn how we're leading with science

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