# A FLEXIBLE APPROACH TO DMPK

QPS' PROVIDES A DEDICATED TEAM OF SENIOR DMPK SCIENTISTS to select, design and conduct adsorption, distribution, metabolism and excretion (ADME) and quantitative whole body audioradiography (QWBA) studies.



# **QPS DMPK OVERVIEW**

Studies determining Absorption, Distribution, Metabolism and Excretion (ADME) characteristics of drug candidates in laboratory animals and humans are an integral part of the Drug Metabolism and Pharmacokinetics (DMPK) services provided by QPS. DMPK projects cover a drug development program from the discovery, candidate selection, Investigational New Drug (IND) enabling, through New Drug Application (NDA) stages.



IND-enabling
Preclinical Studies



Human AME Studies



Radiolabeled ADME Studies



QWBA Studies

#### MACRO & MICRO AUTORADIOGRAPHY

QPS is expert in providing combined mass balance, biliary excretion, PK, and QWBA studies.

- ► Increased efficiency by using a single study protocol
- ▶ Elimination of the possibility of radiolabel degrading over an extended period of time between studies
- Metabolite profiling and identification can be done using the samples from the same study

#### **PROTEIN BINDING**

QPS protein binding studies determine thei extent of protein binding in various species' plasma and tissues.

- ▶ Methods: equilibrium dialysis (RED, Harvard device, 96-well HTD), ultrafiltration, and ultracentrifugation
- ▶ Discovery screening, in vitro protein binding for IND, and ex vivo studies in clinical phases
- ► Experience in compounds with very high binding, stability issues, or non-specific issues





#### **BIOTRANSFORMATION**

QPS biotransformation studies determine how a molecule may be altered by the action of enzymes.

- ► In vitro metabolic stability in hepatic subcellular fractions to determine intrinsic clearance
- In vitro comparison of metabolite formation in animal and human hepatic preparations.
- ▶ In vivo metabolite profiling, identification and quantification to satisfy Metabolites in Safety Testing (MIST)

#### **DRUG-DRUG INTERACTION**

QPS drug interaction studies determine the potential of a substance to alter cytochrome P450 activity.

- ▶ In vitro inhibition characterization
- In vitro mechanistic characterization
- Identification of the reversible mechanism of inhibition
- ▶ In vitro mechanistic characterization
- ► Identification of the mechanism of time In vitro characterization of CYP1A2, CYP2B6, and CYP3A4 induction potential dependent inhibition



### SCIENTIFIC LEADERSHIP AND PROVEN RESULTS



Our dedicated, experienced team ensures that all DMPK studies conducteed at QPS meet timelines and regulatory requirements. QPS provides high quality data along with direct access to our technical staff, regularly scheduled updates in a format that works for you, and prompt and courteous answers to your inquiries at a fair and competitive prices.

- ▶ IND-enabling preclinical studies
- QWBA
- ▶ Radiolabeled ADME
- Human AMF
- Protein Binding







## **OPS IS A GLOBAL CRO WITH LOCATIONS AROUND THE WORLD**



# BENEFIT FROM THE WORLDWIDE RESOURCES THAT A GLOBAL CONTRACT RESEARCH ORGANIZATION BRINGS

Whether your focus is small molecules, protein biotherapeutics, vaccines, gene therapy or cell therapy, QPS provides a full range of bioanalytical services to support all drug development needs from discovery, through clinical development and regulatory filing.





TIME IS OF THE ESSENCE IN DRUG DEVELOPMENT.
CONTACT THE QPS BUSINESS DEVELOPMENT TEAM TODAY!