

A flexible approach to

Radiolabeled ADME Studies

**HAVING ALL OF YOUR RADIOLABELED
ADME STUDIES PERFORMED AT QPS SAVES YOU
TIME, SAVES YOU MONEY, AND SAVES YOU RESOURCES.**

A well-conceived and executed preclinical and clinical radiolabeled ADME program will provide you with a detailed assessment of the total fate (mass balance, route, and rate of excretion, tissue distribution, metabolic pathways, and identity and quantity of metabolites) of your drug candidate to support regulatory submissions.

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

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Which radiolabeled ADME studies can be performed by QPS?

Preclinical Radiolabeled ADME Studies:

- ▶ Mass Balance/Routes of Excretion
- ▶ Quantitative Whole-Body Autoradiography (QWBA)
- ▶ Microautoradiography (MARG)
- ▶ Plasma Protein Binding; RBC/Plasma Distribution
- ▶ *In Vitro* Species Comparison of Metabolism
- ▶ Metabolic Reaction Phenotyping
- ▶ Metabolite Profiling, Identification, & Radio-quantification

Radiolabeled hAME Studies:

- ▶ Consultation and Preparation of Clinical Study Protocol
- ▶ Preparation of human radiation dosimetry
- ▶ Ethics Committee & Competent Authority

Submission; fast review and approval in 14 days after submission

- ▶ Preparation and Release of Radiolabeled IMP According to GMP Annex 13 by a Licensed Radio- pharmacy; this also includes measurement of radiochemical purity
- ▶ Drug Administration of Radiolabeled IMP by a Designated and Radio-licensed Research Physician; Flawless Execution of Study According to Protocol
- ▶ Collection, Processing, and Analysis of Radioactive Human Blood, Plasma, and Excreta (urine, feces, and expired air)
- ▶ Metabolite Profiling, Identification, & Radio-quantification
- ▶ Preparation & Submission of an Integrated Clinical Study Report (CSR)

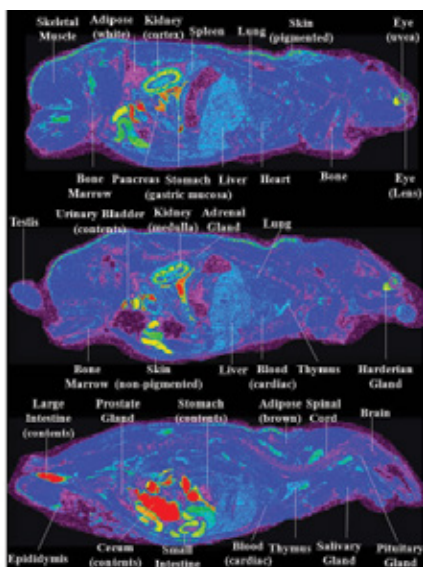
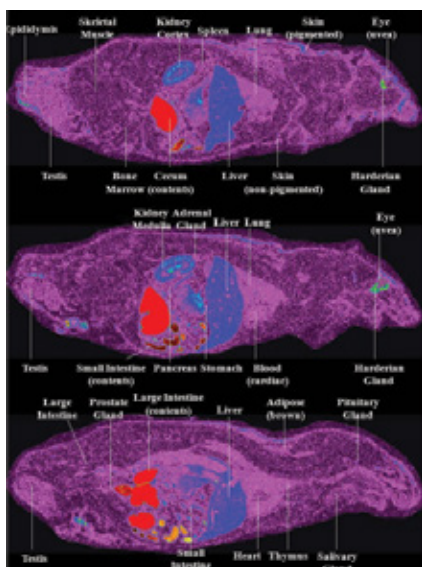
QPS is a True Turnkey ADME Study Provider That Effectively Execute Your Radiolabeled Studies.

By placing your studies with QPS, you will benefit from peer-to-peer communication with our expert ADME scientists who have extensive industry and CRO experience enabling optimal planning and execution of your studies.

A senior technical expert will be assigned to facilitate the rapid development of your drug candidate by shepherding the compound through the various studies within QPS: preclinical excretion/mass balance, QWBA, MARG (if necessary), profiling/

identification/radio-quantification of metabolites, dosimetry calculation, and human mass balance studies.

Any compound specific and/or sample handling procedures will be seamlessly transferred between QPS preclinical and clinical teams to minimize delays at the different stages of drug development which ensures rapid generation and rigorous analysis of preclinical and clinical ADME data resulting in high quality regulatory-filing ready study reports.



Evaluation of Metabolism and Disposition of GDC-0152 in Rats Using ^{14}C Labeling Strategy at Two Different Positions: A Novel Formation of Hippuric Acid from 4-Phenyl-5-Amino-1,2,3-Thiadiazole.

Qin Yue, Teresa Mulder, Patrick J. Rudewicz, Eric Solon, Nageshwar Budha, Joseph A Ware, Joseph Lyssikatos, Cornelis E.C.A. Hop, Harvey Wong, and S. Cyrus Khojasteh. Drug Metab Dispos February 2013 41:508-517.

AGILITY. FLEXIBILITY. SPEED

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QPS is a Global CRO
with locations around the world
to serve the evolving needs of the
Pharmaceutical and Biotech industries

