Quotient Sciences

CLINICAL PHARMACOLOGY

Human ADME studies

Metabolic data for regulatory submission

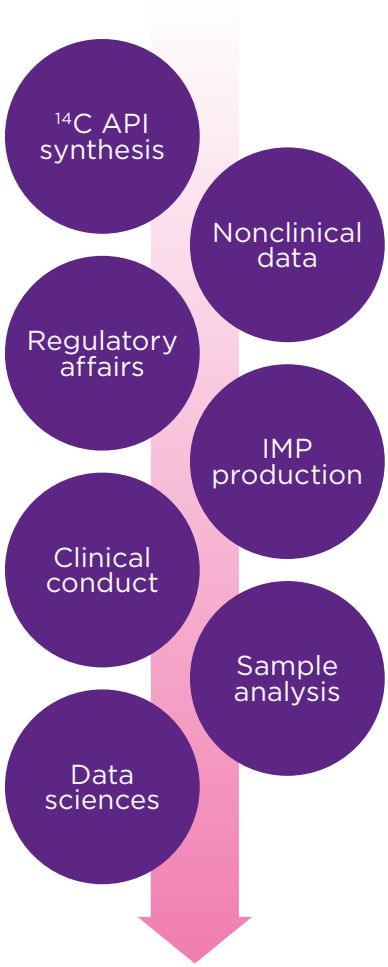
Human ADME studies performed with radiolabeled drugs are an essential part of the regulatory submission package for new chemical entities. If your drug is approaching the end of Phase II clinical development or you are planning for your regulatory submission, Quotient Sciences can help you meet your program goals. With over 30 years' experience as a world leading provider of human ADME 14C radiolabeled studies, we have the scientific expertise and operational know-how to design and deliver human ADME programs in preparation for NDA, MAA and global regulatory filings.

Center of excellence for human metabolic investigations

- World class medical and science teams
- Expertise in reviewing clinical and non-clinical data and designing the human investigation
- Effective study delivery from a combined experience of >300 human ADME studies
- Scientific analysis and interpretation of metabolic data

Modern, comfortable and spacious clinical facilities

- Purpose-built, self-contained human ADME ward and laboratory
- Experienced volunteers who understand the rigors of human ADME studies
- Excellent volunteer recruitment, retention and completion



Human ADME studies

On-site pharmaceutical sciences facilities for the development, real-time GMP manufacture and QP release of ^{14}C drug products

- Supply of oral and parenteral formulations for ADME studies
- GMP manufacture of ^{14}C drug product in the same building as clinical dosing
- Real-time adaptive manufacturing to support ADME studies in patients at specialist clinics

Real-time mass balance data output with cutting edge metabolite profiling and identification capabilities

- Rapid quantitative radiochemical analysis and low level (TopCount) radioactivity counting
- Dedicated metabolite identification and characterization using the latest instrumentation (LTQ Orbitrap XL™ and Q Exactive™)

Facilitated by Synthesis-to-Clinic®, a unique service from Quotient Sciences delivering top quality human ADME data from a single program of work.

About Quotient Sciences

Quotient Sciences is dedicated to accelerating the development of new drugs for patients around the world. We provide formulation development, clinical pharmacology trials, and clinical and commercial manufacturing services to the pharmaceutical and biotech industry. These services are provided either individually or as an integrated service offering via our Clinical Pharmacology platform.

Edinburgh | Miami | Nottingham | Philadelphia | Reading

Call UK: +44 (0)115 974 9000 | Call USA: +1-800-769-3518
info@quotientsciences.com | www.quotientsciences.com

Quotient Sciences