quotientsciences.com

Quotient Sciences

Molecule to cure. Fast.™

Information sheet

Isotope Labelling

Whether you need isotopically labelled (14C/SIL) compounds for non-clinical or clinical metabolism studies and the quantification of materials in biological matrices, our expertise provides the necessary labelled materials tailored to support your studies.

With over 30 years of successful delivery on-site, Quotient Sciences' highly trained chemists have extensive chemical and radiochemical knowledge and the experience required to supply consultancy and advice on the most suitable labelling positions for a variety of molecular entities.

Trust us to deliver on time in, in full – 98% delivery rate at Quotient

What we can do for you

We pride ourselves on accelerating your drug compounds to the clinic. Our team of experts provide guidance on the design and conduct of both non-clinical and clinical human ADME studies for research, development and regulatory purposes. Our radiolabelling expertise is available as a standalone service or as part of our integrated Synthesis-to-Clinic™ offering. Customers who have placed both their non-clinical and clinical studies with us, have shortened their time to clinic and saved on development costs by avoiding the need for re-synthesis.

Applications include

- Ability to safely handle high potency/ high hazard compounds (cytotoxics)
- Synthesis of metabolites & reference materials aiding bioanalytical and metabolism studies
- Degradants and process impurities to support API development
- Route development and precursor synthesis for labelling with ^{3}H and short-lived isotopes ^{11}C and ^{18}F
- Experienced in classical and non-classical synthetic techniques, microwaves reactors, H/D-cubes, automated peptide synthesis, microbiological and bio-catalysis

Why choose Quotient Sciences?

- >30 years successful delivery on-site
- 98% delivery rate with over 200 projects completed
- 14C for non-clinical and clinical studies
- Stable isotope (e.g. ^{2}H, ^{13}C, ^{15}N, ^{18}O) labelled compounds for mass spectroscopy standards

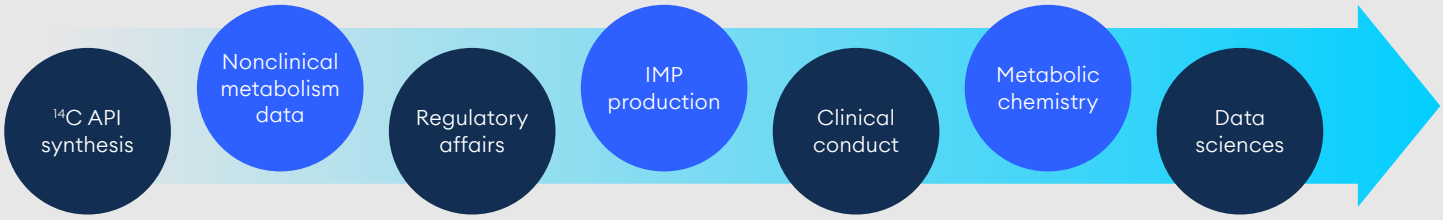
Our state-of-the-art equipment includes:

Vacuum manifold equipment for handling volatile 14C starting materials, HPLC, LC-MS, GC-MS, liquid scintillation counters, radio-TLC imagers and H-Cube flow hydrogenation systems.

Facilitated by Synthesis-to-Clinic®

Our Synthesis-to-Clinic® support – from radiosynthesis to final clinical report – pulls all the necessary elements required for the completion of a human ADME program together into a single, integrated program of work. It drives efficient development and manufacturing of 14C drug products tailored to the specific requirements of your ADME program – including intravenous (IV) products to generate IV pharmacokinetic and absolute bioavailability data, where appropriate. This platform supports your entire ADME program, from radiosynthesis through to clinical reporting, delivering all of these components on your behalf under the guidance of a single Quotient project manager.

A global network of pharmaceutical sciences facilities for the development, real-time GMP manufacture and QP release of 14C drug products enables us to seamlessly supply oral and parenteral formulation of ADME studies. GMP manufacturing of 14C drug product is conducted in the same building as clinical dosing and real-time adaptive manufacturing allows us to support ADME studies in patients at specialist clinics.



14C Radiolabelling

Why choose Quotient?
We are MHRA accredited and offer full GMP synthesis of 14C-labelled compounds for human studies. We are experts in the safe handling of 14C- high potency / high hazard compounds (cytotoxics) and 14C-labelled gases and volatiles, including $14CO_2$.

We support projects through separate, complete syntheses of non-clinical and clinical batches, or by synthesis of a pre-clinical intermediate, which can subsequently be used to prepare non-clinical and clinical batches. The latter approach can avoid the need for re-synthesis, saving our clients' time and reducing costs associated with providing labelled material for human ADME studies.

How do we do it?
Our collaborative approach, facilitated by our all-in-one facility, enables us to draw on the multidisciplinary expertise of a strong analytical and drug product team, delivering a service that helps our customers through all stages of the drug development process. With formulation development, IMP manufacture and dossier writing expertise on-site, we provide greater flexibility for integrating the provision of labelled materials with your development program.

Stable isotope labelling
We provide synthesis of stable-labelled compounds incorporating ^{2}H, ^{13}H, ^{15}N or ^{18}O and have the ability to perform H/D exchange on API or late stage intermediates. The use of stable labelled standards is recommended by EMA (guideline on bioanalytical method validation), AAPS/FDA (BMV Conference Report) and endorsed by the European Bioanalytical Forum and Global Bioanalytical Consortium. Our team has supported numerous bioanalysis studies for a diverse range of molecules and we have the experience required to ensure project success.

Alnwick › Edinburgh › Miami › Nottingham › Philadelphia › Reading

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