



Information sheet

# Bioanalytical Services

**Determining drug exposure is vital for the assessment of drug safety and efficacy. Our Bioanalytical team, develop and refine methods so exposure can be assessed reliably and accurately in a variety of biological matrices.**

At Quotient, our dedicated team consists of globally recognized experts with significant experience of delivering our client's highly challenging projects. Our bioanalytical chemists have over 40+ years of experience in supporting all stages of drug development, from early preclinical through to First-in-Human, Phase I and onwards to Phase II- III studies.

By combining depth of knowledge and the use of state-of-the-art equipment, we can help you develop life changing medicines and take them to market quickly and efficiently.

## What we can do for you?

We are experts in the development, validation and application of bioanalytical assays for small and large molecules, elements and biomarkers. We can help you develop a clearer understanding of what is happening to your molecule as it progresses through the body. Our leading-edge mass spectrometry platforms enable you to both identify and quantify analytes from complex biological matrices, to discover whether your drug is metabolized.

In addition, we can offer expert PK and TK data analysis and reporting, supporting pre-clinical and clinical studies to accelerate your drug development. By working together with our expert Pharmacokinetics team, we can reduce the risk of downstream delays in later phases of drug development.

## Applications include

- > Preclinical TK, bioavailability, PK studies
- > First in man/dose escalation studies
- > Bioanalytical methods for human clinical PK
  - > Clinical pharmacology
  - > Bioavailability
  - > Bioequivalence studies
- > Drug-drug interactions
- > PK/PD studies support
- > Biomarkers

## Why choose Quotient Sciences

- > Short lead times and rapid turnaround
- > >400 methods developed (LC-MS, GC-MS, ICP-MS)
- > Integrated TK/PK analysis and reporting
- > >40 years of scientific expertise
- > GLP & GCP accredited laboratories
- > Expertise in specialist areas: Insulin analogues & polypeptide drugs, elemental analysis, volatile drugs & biomarkers

## Our state-of-the-art equipment includes:

LC-MS/MS, LC-HR-MS, ICP-MS, ICP-MS/MS, GC-MS and GC-MS/MS

## Case studies

### ICP-MS assay for antimony

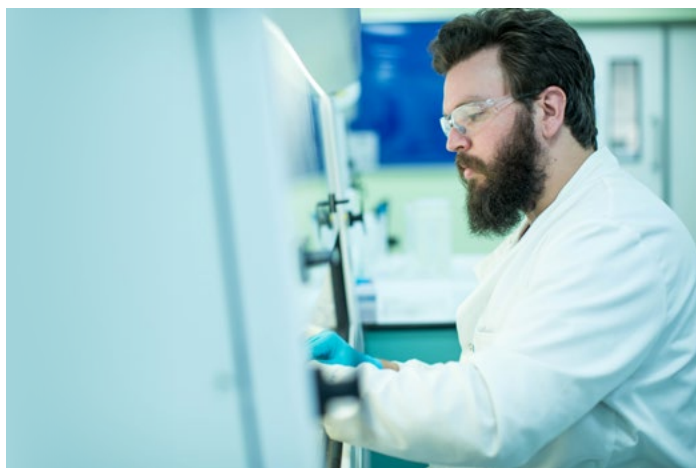
We developed and validated an ICP-MS assay for antimony in human plasma to support the study of antileishmanial drugs in Colombia. The assay was successfully scientifically validated from 25.0 to 10,000 ng/mL for antimony in human plasma and all clinical samples were analyzed with the documented stability period.

### Analysis of aluminum in rat through ICP-MS

We investigated the absorption, distribution and elimination of aluminum in an animal model using ICP-MS. Though aluminum is one of the most challenging elements to detect and quantify at trace levels by ICP-MS, the method found significant aluminum concentrations in subcutaneous dose sites. The results provided further insight into the distribution of aluminum after subcutaneous administration.

### Routine insulin quantification

We developed a hybrid IA-LC-MS/MS method for the routine quantification of insulin, insulin analogues and their biosimilars in clinical trial samples. The methodology has been validated for insulin lispro, glargine and metabolites and further methods are in development for endogenous insulin.



### Who is Quotient Sciences?

Quotient Sciences is a drug development and manufacturing accelerator providing integrated programs and tailored services across the entire development pathway. Cutting through silos across a range of drug development capabilities, we save precious time and money in getting drugs to patients. Everything we do for our customers is driven by an unswerving belief that ideas need to become solutions, molecules need to become cures, fast. Because humanity needs solutions, fast.

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