Bioanalytical Chemistry Services

RTI International provides bioanalytical services to support pre-clinical and clinical studies. Our experienced scientists offer a full range of LC/MS/MS and GC/MS bioanalytical services, from method development, method validation, and GLP sample analysis, to identifying metabolites in biological matrices and impurities in drug products. RTI's familiarity and compliance with regulatory requirements of the U.S. Food and Drug Administration (FDA) and other agencies enable our clients to have complete confidence in the quality and acceptability of all analytical data.

Capabilities

- LC/MS/MS and GC/MS method development and validation
- Metabolite identification
- Impurity characterization
- Biological sample analysis (blood, urine, feces, aqueous humor, tissues, brain, plasma, serum) to support all phases of drug development
- DMPK and toxicology support
- Obesity biomarker platform (~180 analytes)
- In-house synthesis of unavailable compounds (e.g., metabolites, internal standards)

Bioanalytical Expertise

- Method development and validation for a wide spectrum of drug substances
- Quantitative analysis at sub-picogram/mL concentrations
- Chiral separation
- Structural elucidation and metabolite identification
- Determination of acylcarnitine/carnitines, free and total fatty acids, amino acid, acyl-COAs in plasma and liver tissue

Instrumentation

- LC/MS/MS and UHPLC/MS/MS systems with ESI, APCI, APPI, and nanospray ion sources
  - Sciex API 5000, 4000 (2) and 4000 QTrap (2) LC/MS/MS
  - Agilent 6410 LC/MS/MS
  - Thermo Electron LTQ, LTQ ETD, and LCQ Deca LC/MS^n
- High-resolution MS
  - Agilent 6230 LC/TOF
  - Waters Synapt G2 HDMS
  - Thermo Electron LTQ Orbitrap
- GC with FID, ECD, NPD, FPD, and TCD
- GC/MS (Agilent 5975/5973) and GC/MS/MS (Agilent 7000) with EI and CI
- UPLC and HPLC with PDA, UV, ELSD, RI, fluorescence and electrochemical detection
- ICP-MS
- CE with PDA

Additional Resources

- Stable isotope and radiochemical synthesis
- 500 and 300 MHz magnetic resonance spectrometers
- Access to AAALAC-accredited animal facility
- Quality assurance
- DEA Registrations Schedule I–V
- Preclinical toxicology and DMPK testing under FDA guidelines
- Toxicity testing under U.S. Environmental Protection Agency and OECD guidelines

Working Closely with Our Clients

RTI's technical, research, and development services meet the highest standards of professional performance to satisfy the unique requirements of our clients. We work closely with our clients to identify their requirements and clarify their expectations, including cost and time constraints.

Brian F. Thomas, PhD—Dr. Thomas has more than 25 years of experience in analytical chemistry and mass spectroscopy. He oversees the development of chromatographic assays and spectrophotometric assays for the qualitative and quantitative analysis of drug substance and drug products.

Melanie A. Rehder Silinski, PhD—Dr. Silinski has expertise in mass spectrometry more than 10 years of experience in drug discovery and development.

RTI extends its excellence in research and technical services to its business systems and processes, making it easy for clients, subcontractors, and vendors to partner with us. We have the contractual, legal, and business structures to serve any client with projects of all sizes. RTI is a 501(c)(3) nonprofit corporation.

More Information

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