

Bioanalytical Chemistry Services



RTI International provides bioanalytical services to support preclinical and clinical studies. Our experienced scientists offer a full range of liquid chromatography/tandem mass spectrometry (LC-MS/MS) and gas chromatography–mass spectrometry (GC-MS) bioanalytical services—from method development, method validation, and Good Laboratory Practices 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 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 (e.g., blood, urine, feces, aqueous humor, tissues, brain, plasma) to support all phases of drug development
- Drug metabolism and pharmacokinetics and toxicology support
- 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/milliliter concentrations
- Chiral separation
- Structural elucidation and metabolite identification
- Determination of acylcarnitine/carnitines, free and total fatty acids, amino acid, and acyl-COAs in plasma and liver tissue

Instrumentation

- LC-MS/MS and ultra high-performance LC-MS/MS systems with electrospray ionization, atmospheric pressure chemical ionization, and atmospheric pressure photoionization ion sources
 - SCIEX 7500, 6500+ (2), API-5000, 4000 (2), and 4000 QTrap (2) LC-MS/MS
 - Agilent 6410 LC-MS/MS
- High-resolution mass spectrometry and tandem mass spectrometry
 - Thermo IQ-X and LTQ Orbitraps
 - Agilent 6230 TOF
- GC with FID, ECD, NPD, FPD, and TCD
- GC-MS (Agilent 5977/5975/5973) and GC-MS/MS (Agilent 7000) with EI and CI
- Ultra high-performance LC-MS/MS and HPLC with PDA, UV, CAD, ELSD, RI, fluorescence, and electrochemical detection
- Inductively coupled plasma–mass spectrometry
- Sector field inductively coupled plasma–mass spectrometry
- CE with PDA



Additional Resources

- Stable isotope and radiochemical synthesis
- 500 and 300 megahertz magnetic resonance spectrometers
- Access to an Association for Assessment and Accreditation of Laboratory Animal Care International–accredited animal facility
- Quality assurance
- U.S. Drug Enforcement Administration Registrations Schedules I–V
- Shipping and logistics department maintains compliance with U.S. Department of Transportation/International Air Transportation Association standards and has international and customs clearance expertise
- Preclinical toxicology and drug metabolism and pharmacokinetics testing under U.S. Food and Drug Administration guidelines
- Toxicity testing under U.S. Environmental Protection Agency and Organisation for Economic Co-operation and Development guidelines

More Information

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Melanie A. Rehder Silinski, PhD: Dr. Silinski has expertise in mass spectrometry with almost 20 years of experience in drug discovery and development.

Frank X. Weber: Mr. Weber has more than 30 years' experience in trace metals and inorganic chemistry analysis. He has extensive experience as an Analytical Study Director for Good Laboratory Practices studies.

Working Closely With Our Clients

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

Project Highlight

Artificial Joint Monitoring

RTI provided an artificial joint manufacturer with a method to quantify wear metals associated with the joint at concentrations as low as 5 parts per trillion in plasma samples. The ability to quantify metals allowed the manufacturer to get an indication of what component had the most wear and gauge future improvements.

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

www.rti.org

RTI International is an independent, nonprofit research institute dedicated to improving the human condition. Clients rely on us to answer questions that demand an objective and multidisciplinary approach—one that integrates expertise across the social and laboratory sciences, engineering, and international development. We believe in the promise of science, and we are inspired every day to deliver on that promise for the good of people, communities, and businesses around the world. For more information, visit www.rti.org.

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