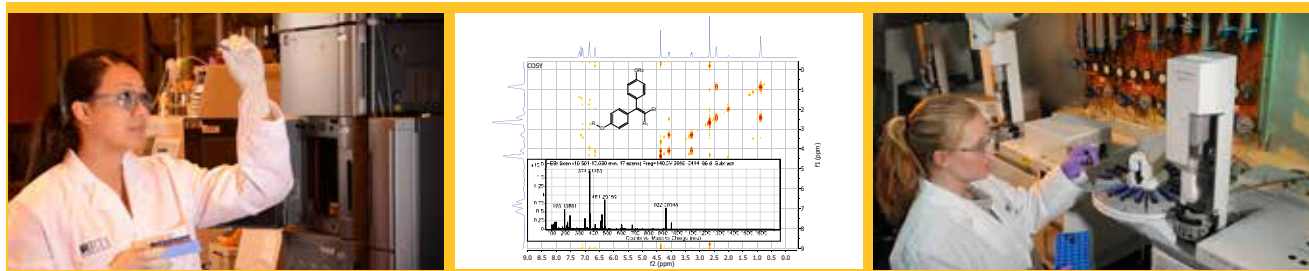


# Analytical Chemistry and Pharmaceutical Development



RTI International provides analytical support and consultation to pharmaceutical, chemical, and biotechnology companies. Our expert scientists offer a full range of analytical services, from lead discovery chemistry to cGMP release of finished 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.

## Preformulation Services

- Solubility, pH, solution stability
- Moisture content, sorption analysis
- Thermal analysis (thermal behavior, melting point)
- Structural characterization—FTIR, UV/Vis, fluorescence, NMR, MS<sup>n</sup>
- Particle morphology, size, and size distribution
- X-ray powder diffraction (XRPD)
- Polymorph screening
- Solid state stability
- Drug-excipient compatibility and packaging component compatibility

## Analytical Services

- Method development and validation for drug substance, impurities, and stability-indicating analysis
- Reference standard characterization, impurity identification, and release testing
- Drug substance characterization—identity, assay, impurities, moisture, pH, residual solvents
- Chiral analysis
- Ion chromatographic analysis
- Excipient characterization—compendial testing

- Drug product characterization—identity, assay, content uniformity, moisture, dissolution
- Test article and dose formulation analysis—purity, homogeneity, and stability
- Stability studies—informal and formal studies (ICH), including elevated, ambient, and subambient temperatures and photostability
- Degradation studies on drug substance and drug product temperature, pH, light, oxidation
- Capability to synthesize impurities available within RTI

## Customized Ancillary Services

- Experimental design approach
- Inventory management
- Repository storage
- Stability storage
- Specialized shipping services
- Chemical synthesis, radiolabeling
- Regulatory consulting

## Compliance

- Registered with FDA as an analytical testing facility
- Registered with DEA for scheduled drug substances
- cGMP/GLP-compliant or R&D-type feasibility studies

## Instruments and Equipment

### Chromatography

HPLC and UPLC with UV, MS, ELSD, RI, fluorescence

Ion chromatography with conductivity, UV

SEC-HPLC with MALS/UV/RI

Capillary GC with FID, NPD, TCD, ECD, MS

Capillary electrophoresis (CZE, cIEF, SDS-PAGE) with UV

Mass Spectrometry

Validated and research LC/MS systems (Trap, Q-Trap, TOF, Orbitrap)

High-resolution MS, MSn, MS/MS, ion mobility

ICP–high resolution MS

### NMR

Multinuclear and heteronuclear, 1D and 2D

300 MHz (hetcorr)

500 MHz (grCOSY, TOCSY, NOESY, ROESY, grHSQC, grHMBC, DEPT135)

### Spectroscopy

UV/Vis and FTIR

Polarimetry and refractrometry

Circular dichroism and fluorescence

### Physical and Ancillary

pH meter

Karl Fischer

DSC, TGA, VTI-SA

Rheometer

Optical microscope with hot-stage and digital imaging

Particle size distribution (laser, sieve)

Dissolution apparatus (USP, apparatus 1 and 2)

Disintegration apparatus (USP)

ESEM

XRD

### Other Equipment

ICH storage freezers, refrigerators, and stability chambers with automated monitoring

Photostability chamber

Laminar flow hoods

Stand-alone barrier facility for toxic compounds

### Leadership Team

- **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 and spectrophotometric assays for the qualitative and quantitative analysis of drug substances and drug products.
- **Melanie A. Rehder Silinski**, PhD—Dr. Silinski has expertise in mass spectrometry and chromatography with more than 10 years of experience in drug discovery and development, from early exploratory research through investigational new drugs.

### 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.

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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