RTI International provides trace inorganic bioanalytical method development, method validation, and method transfer services for state and federal agencies, as well as pharmaceutical and commercial clients. With a staff of experienced scientists and state of the art laboratories and equipment, RTI also solves complex and unique impurity characterization challenges.

**Capabilities**

- Innovative bioanalytical method development
- Method validation and sample analysis for single- or multiple-analyte panels
- Method transfer services
- Facilities designed to prevent environmental contamination
- Experience with challenging matrices:
  - Urine and feces
  - Plasma, serum, and whole blood
  - Tissues (kidney, liver, muscle, brain, digestive tract)
  - Hair, bone, and nail
- Screening of collection media to inform study design
- Trace element, metalloprotein, and organometallic analytes
- Experienced analytical staff trained to support regulated studies
- Multiple validated systems:
  - Inductively coupled plasma optical emission spectrometry (ICP-OES, 2)
  - Inductively coupled plasma mass spectrometry (ICP-MS, 2)
  - Microwave digestion (5)
- Additional systems:
  - Sector-field, high-resolution ICP-MS
  - Energy dispersive X-ray fluorescence (EDXRF, 5)
  - Wavelength dispersive X-ray fluorescence (WDXRF)
  - Ultra performance liquid chromatography (UPLC); coupled with ICP-MS/OES for speciation
  - Cold vapor atomic fluorescence spectrometry (CVAFS); ultra-trace level Hg
  - Microscopy: SEM, TEM, OM
  - X-ray diffraction (XRD)
  - Fourier transform infrared spectrometry (FTIR)
  - Thermogravimetric analysis (TGA)

**Case Study in Bioanalytical Method Development, Validation, and Analysis**

**Client Problem:** A major pharmaceutical client needed an ultra-trace measurement of a rare earth element in human clinical samples. Such measurements required compliance with U.S. Food and Drug Administration’s Good Laboratory Practices.

**RTI Solution:** Within 30 days, RTI developed and validated an accurate, rapid, sensitive method for the client and subsequently analyzed over 20,000 clinical samples.
Case Study for Bulk Mineral Content Method Validation

**Client Problem:** A major pharmaceutical client needed to show variations of essential minerals in dosed and placebo subjects treated with multiple formulations (e.g., tablet, capsule) in support of the development of a new drug product. This study required compliance with the U.S. Food and Drug Administration’s Good Laboratory Practices.

**RTI Solution:** RTI developed and validated an analytical method for five essential elements in human feces by ICP-OES and subsequently analyzed over 5,000 samples for variation of mineral content related to dosing in support of the development of a new drug product.

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Case Study for Hexavalent Chromium

**Client Problem:** A government client sought to determine if hexavalent chromium was carcinogenic when present in drinking water.

**RTI Solution:** RTI developed and validated methods for the determination of chromium in several biological matrices, including rodent urine, feces, kidney, liver, red blood cells, plasma, fore stomach, and glandular stomach. Validated methods were used to determine concentrations in thousands of samples, and hexavalent chromium was established as a likely carcinogen in drinking water by the client.

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Case Study in Multiwalled Carbon Nanotube Physiochemical Characterization

**Client Problem:** A government client needed to characterize several commercially available MWCNT samples prior to their use in toxicological studies.

**RTI Solution:** RTI determined length, diameter, morphology, residual metal catalyst content, and amorphous and structured carbon impurities in a suite of commercially available MWCNT samples. The most appropriate samples were then selected by the client for further study and functionalization.

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