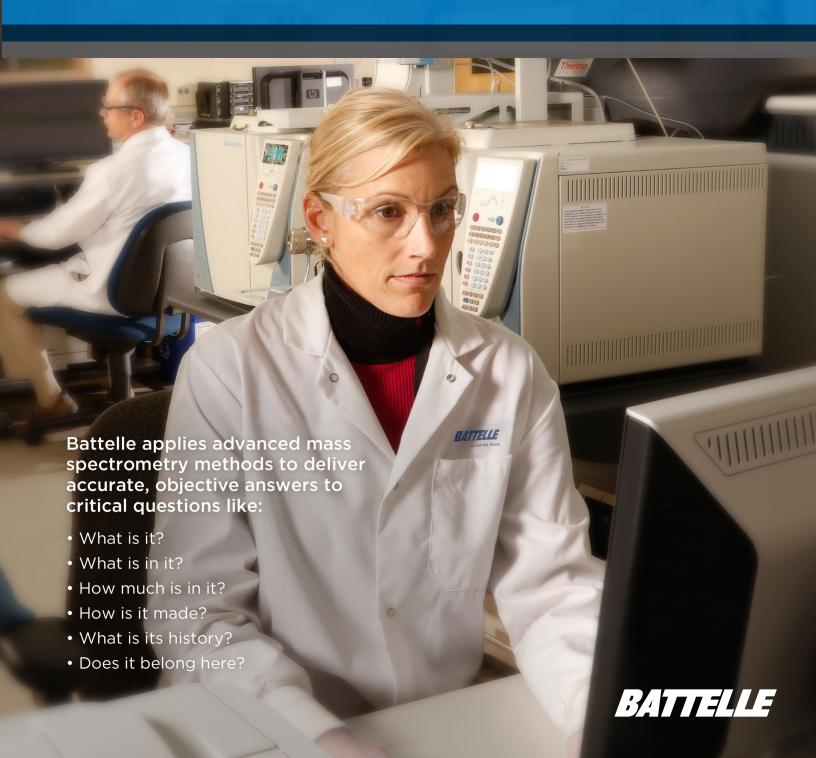
Mass Spectrometry

SOLVING PROBLEMS WITH ADVANCED ANALYTICAL METHODS





DON'T SETTLE FOR DATA. DEMAND ANSWERS.

When the answers really matter, count on Battelle.

At Battelle, you'll find world-class expertise and equipment for mass spectrometry—and a whole lot more. Our research teams do more than run standard analytical tests. We apply deep subject matter expertise in analytical chemistry and related disciplines to solve problems.

Battelle brings together highly experienced and credentialed staff, including Ph.D.-level analytical chemists, organic chemists and biochemists, to design mass spectrometry studies tailored to your specific questions and applications. We can also reach back across Battelle for subject matter expertise on a broad range of scientific and technical topics, including advanced materials development, applied genomics, toxicology, advanced data analytics, medical devices, public health, cyber security, and chemical, biological and explosives defense.

It's this combination of expertise that allows us to deliver highly accurate results and help you understand what your data are telling you. Our holistic approach to analytical challenges allows us to identify the root cause and solve your problems efficiently and effectively. We provide:











Our Markets

We apply advanced mass spectrometry methods to solve critical problems for:

- Environmental assessment and monitoring
- Chemical forensics and sample attribution
- Hydrocarbon forensics
- Consumer product formulation and failure analysis
- Agrochemical formulation and registration
- Toxicology and exposure studies
- Tobacco and nicotine product characterization
- Food and beverage analysis and ingredient verification
- Chemical, biological and explosive weapons defense.

Our Quality Processes

Battelle's varied client base has provided us with the opportunity to develop, adapt and succeed in implementing Quality Management Systems (QMS) that are compliant with a variety of quality standards, regulations and programs. Organizations within Battelle have individually tailored and adapted Battelle QMS to meet the requirements of many nationally and internationally recognized standards to serve the specific needs of our customers, including but not limited to:

 ISO 9001, Quality Management Systems-Requirements

- ISO 14001, Environmental Management Systems-Requirements
- ISO 17025, General requirements for the competence of testing and calibration laboratories (see scope statement posted on the American Association of Laboratory Accreditation website)
- ISO 13485, Medical devices-Quality management systems-Requirements for regulatory purposes
- ASME NQA-1, Quality Assurance Program Requirements for Nuclear Facilities
- Food and Drug Administration (FDA) quality regulations (e.g., GLP, cGMP, 21CFR Part 820, 21CFR Part 11, 21CFR Part 58)
- Environmental Protection Agency (EPA) quality regulations (e.g., NELAC, GLP - 40 CFR Part 160 and 40CFR Part 790, specific EPA Quality Assurance Project Plans)
- CMMI (Capability Maturity Model Integration)
- Custom Project/Customer Quality Assurance Project Plans (QAPPs)

Battelle has extensive experience in quality requirements analysis, QMS development and QMS training and implementation having developed and continually improved the Battelle QMS for the last 30-plus years.



Our Capabilities

Battelle applies advanced mass spectrometry methods to deliver precise, accurate answers to critical questions like:

- What is it?
- What is in it?
- How much is in it?
- How is it made?
- What is its history?
- Does it belong here?

We have the facilities, experience and regulatory permits to work with even the most challenging analytes and matrices. Our researchers can work within any needed quality system, including Good Laboratory Practice (GLP) and ISO 9001. Battelle's specialties include:

- Ultra-low detection of trace-level constituents or contaminants
- Analysis of complex mixtures and matrices
- Chemical fingerprinting for source attribution
- Analysis of highly toxic/dangerous substances such as chemical and biological weapons, illicit drugs and explosives.

Study Design and Method Development

Every study at Battelle starts with a thorough understanding of the questions you need to answer and the data required to answer them. Rather than simply running standard analyses, we help you determine the most efficient approach to getting the data you really need. Our experienced team of study directors and investigators will work with you to design a study around your requirements, including sampling methods, analytical techniques and data interpretation and reporting. If appropriate sampling or analytical methods do not exist, we can help you develop and validate new methods to get the answers you need.

Standard Analytical Reference Material Synthesis

Battelle offers a team of organic chemists with advanced degrees and experience in designing and executing custom syntheses, including stable-isotope labeled materials. Battelle organic chemists are skilled in the synthesis and characterization of highly bioactive compounds (including toxins and toxic chemicals). Areas of expertise include natural products, heterocyclic chemicals, alkaloid chemicals, aromatic chemicals, polymeric macro-molecules (including dendrimers and hyper-branched polymers), pesticides, organophosphorus compounds and pharmaceuticals, including fentanyl and related compounds. Battelle routinely synthesizes standard analytical reference materials with purity of 95 percent or greater in both small (milligrams) and large (100 gram) quantities that are not commercially available.



- LC-HRMS
- GC-HRMS
- GC×GC-HRMS
- GC-MS
- GC×GC-TOFMS
- LC-MS/MS

Selected Matrices

We work with a broad range of matrices, including environmental samples, complex mixtures and a comprehensive array of biological samples. Some of our experience includes:

- Soils & sediments
- · Water & other liquids
- Oils
- · Biological tissues
- Excretions
- Foods and beverages
- Air
- · Textiles.

- GC-MS/MS
- ICP-MS
- GC²-HRMS
- GC-MSGC-MS
- GC-MS/VOA
- PTR-MS

Selected Analytes

Our experience spans a wide spectrum of industrial chemicals, environmental contaminants, food ingredients and other substances, including:

- Hydrocarbons
- Persistent organic pollutants (POPs)
- Per- and poly-fluorinated alkyl substances (PFAS)
- · Food additives and ingredients
- Polymers
- Metabolites
- · Chemical and biological agents
- Nutraceuticals
- · Pharmaceuticals.



Our Experience

For more than 85 years, commercial and government clients have counted on Battelle for objective, accurate analytical data and innovative solutions to their most challenging problems. Here are some recent examples of our experience.

Hydrocarbon Forensics

When crude oil or petroleum products are found where they don't belong, accurate source attribution is critical. Is it biogenic or anthropogenic? What is the likely origin? How old is it? Battelle uses multiple mass spectrometry methods along with other analytical techniques to develop precise chemical fingerprints of hydrocarbon samples and find differences between samples that other labs may miss. We accurately quantify, identify and attribute hydrocarbons found in sediment, water and biological tissues—even when samples are highly weathered. Our hydrocarbon forensics team has provided objective analysis for multiple investigations of suspected pipeline leaks, offshore oil spills and accidental releases of gasoline and other petroleum products.

Environmental Assessment, Monitoring and Source Attribution

Whether you need accurate quantification of known contaminants or identification of an unknown substance, the Battelle environmental analytics team can help. Battelle has long provided analytical services to support environmental programs for the U.S. Environmental Protection Agency (EPA), U.S. Navy and U.S. Army Corps of Engineers (USACE), along with many commercial clients.

We use mass spectrometry to support studies for fate and transport modeling, source identification, site characterization, assessment of remediation efficacy, long-term monitoring and agrochemical residue studies. Our researchers provide ultra-trace detection and quantification for a broad range of environmental contaminants, including pesticides, PFAS and hydrocarbons, and are leading the way in development of new methods for emerging contaminants of concern.

Complex Mixture Analysis

From foods and beverages to tobacco products, Battelle can help you accurately characterize highly complex mixtures using advanced analytical chemistry techniques such as mass spectrometry. We provide analysis for regulatory support as well as for supply chain validation (is this what they said is was?), contaminant detection (is something here that isn't supposed to be?) and forensic product investigation (what has changed in my formulation or ingredients that is causing a change in product quality?). A food manufacturer came to Battelle for help in demonstrating statistical equivalence of a new food product formulation for regulatory purposes. After phasing out an ingredient of concern, the manufacturer needed to demonstrate that the new formulation was statistically equivalent to the old formulation with the exception of the missing ingredient. Our analysis, which provided detailed chemical fingerprints of both the new and old formulations, allowed them to successfully demonstrate that the product changes did not necessitate a new round of testing and regulatory submission.



Chemical and Biological Agent Analysis

Working with highly toxic chemical and biological agents presents risks that many labs are not prepared to handle. Battelle has the experience, facilities and regulatory permits to work with even high-hazard or restricted materials. Our analytical capabilities support toxicology studies for the development of new medical countermeasures as well as testing of protective equipment. In a project for the Department of Defense (DoD), Battelle used mass spectrometry to evaluate the protective value of suits intended for use by warfighters in areas with high risk of exposure to nerve agents. Because these substances are so hazardous, we needed a way to accurately detect and quantify permeation of the agent through the material at ultratrace levels. The research team created specialized methods for preparing the samples as well as a containment system for the mass spectrometry equipment to protect analysts working with the materials. Our solution provided simultaneous detection of high and low concentrations of the target agent under a variety of controlled environmental conditions. Our methods allowed us to provide DoD with precise and accurate prediction of how the materials would perform under real-world exposure conditions.

Failure Analysis

At Battelle, we use mass spectrometry to help companies solve a variety of product problems, including material failures, formulation issues and product quality challenges. We can draw on subject matter expertise in advanced materials, polymers, product formulation, engineering and other related subject areas to go beyond laboratory testing. We'll help you understand the data to pinpoint the probable cause of a product failure and recommend changes in ingredients or processes to fix the problem. Our team can answer questions such as:

- Has there been a change in the composition of raw ingredients we are getting from our suppliers?
- What is this unknown additive, and how is it impacting product quality?
- How does a new additive or a change in manufacturing processes impact the stability and molecular structure of our final product?

We use advanced analytical techniques such as mass spectrometry, including both GC and LC scanning electron microscopy (SEM), and optical spectroscopies to provide a more complete and accurate picture of the chemical makeup of your materials or formulations. Our materials failure team also has extensive expertise in accelerated aging and can develop and validate new methods to help you understand how your products will age over time and in different environmental conditions.

Who is Battelle?

We are the world's largest independent, non-profit research and development organization, operating at the forefront of scientific discovery. For decades, both government agencies and leading companies have counted on Battelle to advance their missions. Battelle has a substantial management role at seven national laboratories; six for the U.S. Department of Energy and one for the U.S. Department of Homeland Security. As a non-profit institution, we reinvest all of our profits into philanthropy, education and original research that advances science and technology for the benefit of humankind.

Battelle applies cutting-edge mass spectrometry methods to some of today's most complex challenges. At Battelle, you'll find:

Expertise: We bring together leading experts in analytical chemistry, biochemistry, toxicology, environmental science, data analytics, engineering and a host of related disciplines to develop multidisciplinary approaches to analytical problems.

Experience: Our analytical team has applied mass spectrometry to a broad range of problems for both government and commercial clients, from environmental characterization to product formulation.

Objectivity: Our research is grounded in solid, objective science and proven methods. We provide accurate, trusted data and precise analysis to guide decisions for product development, public policy and regulation.

What can we solve for you today?

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Every day, the people of Battelle apply science and technology to solving what matters most. At major technology centers and national laboratories around the world, Battelle conducts research and development, designs and manufactures products, and delivers critical services for government and commercial customers. Headquartered in Columbus, Ohio since its founding in 1929, Battelle serves the national security, health and life sciences, and energy and environmental industries.

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