CHEMICAL ANALYSIS FOR TOBACCO PRODUCTS

Accurate, Objective Answers for Product Quality, Safety and Regulatory Submission

From new product types to new flavor profiles, the market for tobacco and nicotine products is changing. So is the regulatory environment in which these products exist.

Battelle can provide you the answers you need to ensure product safety and quality and prepare for regulatory submission for your tobacco product—including navigating potential new rules for regulation of flavors in tobacco and electronic nicotine delivery systems (ENDS) products.

THE BATTELLE ADVANTAGE

Our analytical chemistry team combines unique experience that goes far beyond that found in most testing laboratories. We do more than standard analyses. We also develop novel methods to address complex challenges and provide meaningful interpretation of your data for actionable results. Battelle provides:

- 50+ years of experience studying a broad range of tobacco and alternative nicotine delivery products, including product characterization, exposure studies, toxicology and behavioral studies
- State-of-the-art instrumentation and analytical methods for accurate, sensitive and precise chemical analyses
- Extensive experience in immunochemistry, *in vitro* metabolism and other biochemical analysis methods to support inhalation toxicology studies
- A long history of work in highly regulated environments (including pharmaceuticals, medical devices and combination drug delivery devices) and proven experience in assisting our clients in preparing submissions for regulatory approval

Tobacco and Nicotine Product Experience

- Combustible products (cigarettes, cigars, etc.)
- Water pipe/hookah
- Smokeless tobacco products
- Oral nicotine products (lozenges, etc.)
- Electronic Nicotine Delivery Systems (ENDS) (e-cigarettes, vapes)

VALIDATED REGULATORY-COMPLIANT CHEMICAL ANALYSES

Battelle applies analytical chemistry to product characterization for all types of tobacco products, including ENDS, oral nicotine delivery products and combustible tobacco products. Our tobacco team conducts validated, regulatory-compliant chemical measurement methods to meet nicotine and tobacco product quality and safety requirements. We deliver:

- Characterization of complex mixtures of compounds and decomposition byproducts in liquid, smoke, vapor, aerosol and condensed phases
- Isolation, identification and quantification of harmful and potentially harmful constituents (HPHCs) in complex mixtures
- Quantitative analyses of toxic particulate matter in aerosols, including metal nanoparticles
- Quantification of tobacco-specific nitrosamines (TSNAs)
- Analysis of common biomarkers for combustible cigarettes and ENDS products, including biomarkers associated with specific flavorings

BATTELLE

NOVEL CHEMICAL ANALYSIS AND METHOD DEVELOPMENT

In addition to standard chemical analyses, Battelle innovates and develops new analytical approaches to improve testing sensitivity, precision and speed. Some recent examples include:

- Battelle developed a faster approach to quantifying constituents in e-liquids using proton nuclear magnetic resonance spectrometry (1H NMR). Our 1H NMR method was successfully demonstrated on several high sales-volume e-liquids.
- Battelle created a novel method to improve the characterization of complex mixtures. Our method uses comprehensive two-dimensional gas chromatography with time-of-flight mass spectrometry (GC×GC-TOFMS) to provide more robust detection and identification of unknown compounds in complex mixtures compared to traditional GC/MS, offering a more comprehensive picture of the chemical composition of e-liquids, including flavorings and additives.
- Battelle developed a method using high-sensitivity proton transfer reaction-mass spectrometry to conduct real-time, puff-resolved characterization of volatile organic compounds (VOCs) from e-cigarette emissions. Our method includes characterizing both the combined gas and aerosol/particulate phases. Traditional methods only capture the material that is present in either the gas or the aerosol/particulate phase of the generated puffs. Our method has been used to analyze the combined puff streams from commercially available e-cigarettes to identify HPHCs.

END-TO-END SOLUTIONS FOR THE TOBACCO INDUSTRY

Battelle offers a comprehensive suite of services for tobacco companies. We design and execute studies that give you the answers you need to make business decisions, improve the safety and quality of your products and maximize your chances of a smooth regulatory submission.

Product and Device Development

- Verify product formulations for quality assurance
- Test for shelf stability and reactions with device components (e.g., leachables/extractables)
- Identify HPHCs in product formulations and byproducts produced during combustion or heating

Nonclinical and Clinical Studies

- Identify, detect and quantify biomarkers of concern in blood, urine, saliva, breath and tissue for nonclinical and clinical studies
- Conduct analyses to support exposure studies (inhalation toxicology, second-hand/third-hand exposure)

Social Science

- Connect behavioral factors with biomarker analyses to build a more complete picture of product pharmacokinetics/ pharmacodynamics (PK/PD)

Post-Market Surveillance

- Conduct failure/root cause analysis for investigations of adverse events
- Provide support for product reformulation to address problems with product safety, stability or performance

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. For more information, visit www.battelle.org.

800.201.2011 | solutions@battelle.org | www.battelle.org

BATTELLE
It can be done

ID 647 06/18