Regulatory Support for Tobacco Products

Feeling daunted by the regulatory process for tobacco products? Don't worry—Battelle can help.

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PREMARKET TOBACCO APPLICATIONS (PMTA)
SUBSTANTIAL EQUIVALENCE APPLICATIONS (SE)
HUMAN FACTORS STUDIES
OUR SERVICES
MODIFIED RISK TOBACCO PRODUCT APPLICATIONS (MRTP)
PRECLINICAL AND CLINICAL STUDIES
INVESTIGATIONAL TOBACCO PRODUCT APPLICATIONS (ITP)

At Battelle, we've been studying tobacco and nicotine products for more than 50 years and have a deep understanding of Food and Drug Administration (FDA) regulatory requirements. Our experienced team can help you navigate the regulatory process with confidence and find the fastest (and most economical) path to market approval.

The Smoothest Path to Approval Starts at Battelle.

Expert Guidance to Streamline Project Timelines

Battelle does more than just conduct standard studies. We provide comprehensive services for tobacco product manufacturers to guide you at every step along the way to market approval. From data collection to application submission, our team will make sure you fully understand the FDA's compliance policies, application requirements and timelines so you can make informed, strategic decisions.

Trusted Results, from the Lab to Clinical Studies

Battelle has operated at the forefront of nicotine and tobacco research for decades. Our research experience spans the full range of tobacco products available, including cigarettes, cigars, smokeless tobacco, waterpipes, electronic cigarettes (e-cigarettes), many other types of Electronic Nicotine Delivery Systems (ENDS), heated tobacco cigarettes and other products.

Battelle brings together experts from a broad range of disciplines—including chemistry, bioinformatics, economics, engineering, mathematics, medicine, psychology, pharmacology, statistics and toxicology—to provide high-quality, defensible data and to find novel solutions for out-of-the-ordinary research challenges.

The Battelle team brings together expertise in preclinical and clinical tobacco research, human factors studies, analytics and product engineering to analyze your product and help you find the fastest path to market approval.

We are uniquely positioned to provide expert guidance on how to bridge and leverage published data to develop the case for premarket tobacco applications (PMTA), minimizing the need for new clinical data collection. Our approach helps clients reduce project timelines and prioritize research efforts where primary data collection is required.

Science to Support Tobacco Product Applications

Battelle offers a full suite of analytical, preclinical and clinical services to support the regulatory process. Our study directors and staff have extensive experience in designing and conducting studies required for market approval.

Literature Analysis to Support Bridging and Premarket Tobacco Applications

We use advanced analytical methods to scan the available literature for published studies that provide evidence for Premarket Tobacco Applications (PMTA). The algorithm automatically extracts and represents the knowledge contained in scientific, technical or general text in a form that enables complex query and knowledge discovery/visualization. This allows us to streamline the process of finding and leveraging data for a PMTA and discover connections hiding in large bodies of published studies.

Product Characterization and Analyses

We apply, develop and validate regulatory-compliant chemical measurement methods to characterize product components, ingredients, additives and flavors. Our staff conduct highly accurate and reliable chemical analysis for precise measurement of volatile and semi-volatile organic compounds (VOCs/SVOCs), heavy metals, particulates and tobacco-specific nitrosamines in complex mixtures, including vapors and aerosols.

Toxicology Studies

The Battelle Inhalation Toxicology Center has the expertise and experience you need to move products through the regulatory process quickly and efficiently.

We are among the largest specialized *in vivo* laboratories in the United States, with more than 30 years of experience conducting specialized inhalation toxicology studies for government and commercial clients in the pharmaceutical, agricultural, chemical and tobacco industries. We provide accurate, objective data for preclinical toxicology studies under regulatory-compliant (FDA) guidelines.

Preclinical and Clinical Participant Studies

For decades, we have operated at the forefront of nicotine and tobacco research. We conduct both preclinical and clinical participant studies at our specialized facilities to collect data on user behavior, abuse liability, nonclinical health risk, human health impact and biomarkers of exposure. Our studies are designed to help you understand how product characteristics, user behavior and exposure interrelate so you can make informed decisions and gather the data you need to support market approval.

Human Factors Studies

We can help you understand pre-market evaluation and post-market activities. Our human factors team will guide you on how product design and labeling impact user behaviors, including initiation, cessation and dual use, as well as consumer perceptions and risks.

Our Facilities

Our tobacco product research is conducted in state-of-the-art facilities in Baltimore, MD, and Columbus, OH, that are compliant with Good Laboratory Practice (GLP) and Good Clinical Practice (GCP). We have unique experimental chambers designed to safely test tobacco products and rigorously assess environmental exposure. Our facilities house some of the most sophisticated analytical equipment in the world, including puff topography systems, laboratory-based smoking machine devices and breath analyzers for highly accurate quantitative data collection. Our facilities include:

- Preclinical facilities at a state-of-the-art toxicology center with leading experts in inhalation study design to deliver end-to-end solutions
- Clinical laboratories with specially ventilated air circulation systems, allowing for vaping and combustible product smoking indoors
- Bench laboratories utilizing state-of-the-art organic and inorganic analytical instruments and innovative characterization technologies
- Environmental exposure chambers that offer a contaminant-free environment
- Human factors laboratory where experts conduct usability analysis, cognitive psychology and product design research.

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.

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