

# INHALATION TOXICOLOGY



## Precise, Accurate Answers for Drug Development and Occupational Exposure

For expert help with your most difficult inhalation study challenges, trust Battelle. We bring together world-class laboratory facilities with leading experts in inhalation study design, engineering, and exposure to deliver end-to-end solutions for FDA approval in compliance with Good Laboratory Practice (GLP) and EPA regulations.

### ONE STOP FOR ALL YOUR INHALATION NEEDS

We offer a comprehensive suite of standard inhalation toxicology studies as well as custom solutions to address unique problems. Our experts can design, test and characterize novel inhalation delivery systems, develop new methods of aerosolizing compounds, and determine precise dosing concentrations for your study requirements.

### BATTELLE DELIVERS

- Testing capabilities for all laboratory species
- High-throughput testing in a highly controlled, GLP-compliant facility
- Automated and semi-automated systems for data acquisition and control available for studies needing a high degree of precision
- High-containment testing facilities for highly infectious pathogens (BSL-3) and high-hazard chemical agents
- In-house pathology and chemistry staff and laboratories for end-to-end service, including pharmacokinetic and pharmacodynamics studies
- Proven experience in navigating the FDA approval process and EPA study requirements
- Laboratory capacity for high volume of inhalation studies with 12 rooms specified for inhalation exposure, and additional rooms capable of inhalation exposure made available as needed.

Whether you require data to progress a new therapy through FDA approval or need to quantify exposure risks for an industrial chemical, we can design a study that meets your needs. We have extensive experience with a broad range of small molecules, therapeutics and chemicals, including biologics, anesthetics, asthma therapies, antibiotics and antivirals, microorganisms, and more. Our staff includes experts in the generation and characterization of biological agents (bacteria, viruses, and toxins), chemical agents, cigarette smoke, electronic cigarette vapor, and nanoparticles.

### Safety Pharmacology

Obtain objective, accurate answers to meet FDA safety testing requirements for your new drug or therapy. We can help you progress through the regulatory process with confidence.

### Pharmacological Efficacy Testing

Determine the efficacy and dosing requirements for novel drugs and biologic therapies. We deliver end-to-end solutions for all required species to help you streamline your pre-clinical testing needs.

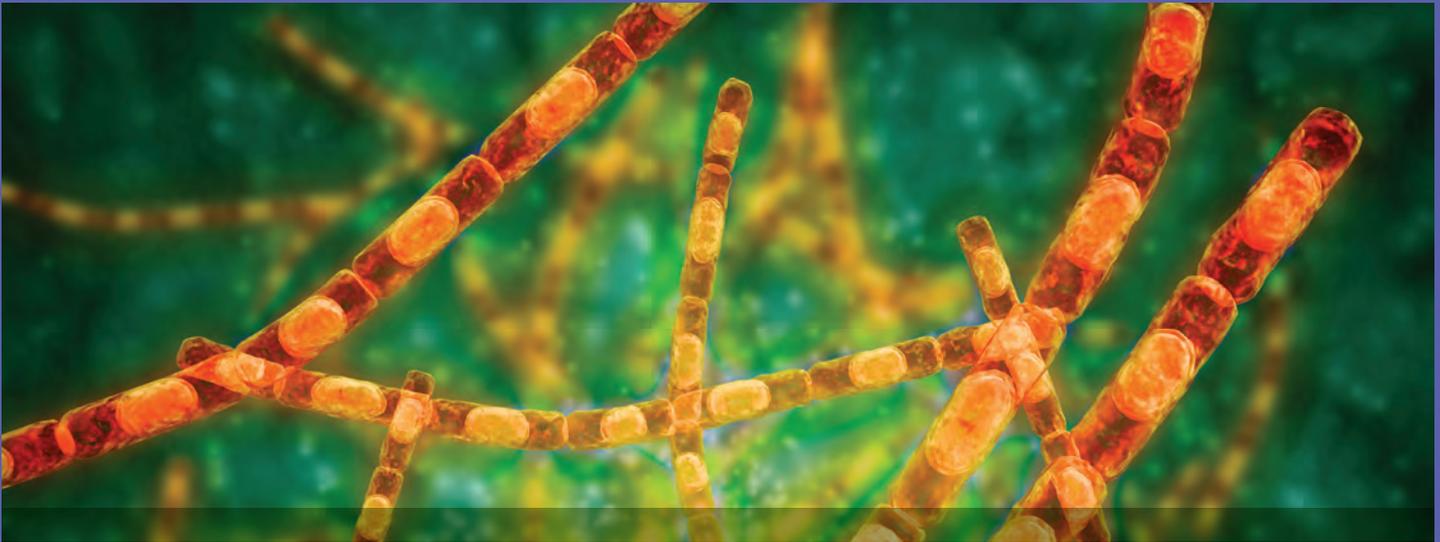
### Occupational Exposure

Quantify the exposure risks of a chemical with traditional inhalation or whole-body exposure testing. We can deliver the data you need to set safe exposure limits, mitigate risks and meet EPA regulatory requirements.

### Inhalation Toxicology Capabilities

- Nose-only inhalation
- Head-only inhalation
- Whole-body exposure
- Cardiovascular and respiratory telemetry
- Neurobehavioral evaluation





### Fast-Track Efficacy Studies for a Novel Anthrax Treatment

Battelle performed inhalation studies to demonstrate the effectiveness of a new therapy for inhalational anthrax, an infectious disease caused by breathing in spores of the bacterium *Bacillus anthracis*. Raxibacumab is a protein-based monoclonal antibody treatment. It recognizes and neutralizes the toxins produced by *Bacillus anthracis*. Left untreated, these toxins can cause massive and irreversible tissue damage and death. Anthrax is considered a potential bioterrorism threat, making discovery of effective treatments an urgent priority for the U.S. Government. However, because it is a rare and lethal disease, it was not possible to conduct human trials. Studies were performed under FDA fast track designation and priority review using the FDA Animal Rule. Battelle completed four studies, using two different species, to demonstrate the efficacy of the treatment and determine appropriate dosing recommendations. Raxibacumab has since been approved by the FDA. It was the first monoclonal antibody to be approved under the FDA animal rule.

### Ready to learn more?

Contact us today at [solutions@battelle.org](mailto:solutions@battelle.org) or 1.800.201.2011 to talk with a study design expert.



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](http://www.battelle.org).

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**BATTELLE**

It can be done