



# INHALATION TOXICOLOGY

Pharmaceuticals Chemicals Agrochemicals Consumer Products

IITRI is a premier provider of inhalation toxicology services to the pharmaceutical, biotechnology, chemical, agrochemical, and consumer products industries. We have over 40 years of experience aerosolizing solids, liquids, gasses, or metered dose inhaler formulations to generate and characterize a well-controlled test atmosphere for your study. We have also conducted large inhalation toxicology studies of cigarette smoke and electronic cigarette (Ecig) vapors and flavors.

Our technical team includes PhD aerosol scientists and DABT study directors, along with highly experienced technicians. Our 110,000 sq. ft. facilities include specialized inhalation suites for small and large animal studies, and our on-site bioanalytical laboratory ensures rapid method development and analysis of biological tissues and fluids. Inhalation studies are conducted in accordance with testing guidelines of the FDA, EPA, OECD, and other international regulatory agencies.

We work closely with you to develop a personalized program to meet your specific needs, including non-standard and customized studies. Our hands-on study directors are highly accessible, personally connecting you to your study from start to finish.

## TEST ARTICLES

- Gas or vapors
- Liquids
- MDI formulations
- Powders
- Fibers
- Nanoparticles
- Chemicals
- Aerosols by combustion
- Aerosols from radiolabeled materials
- Smoke or vapors from tobacco products

## EXPOSURES AND DOSING

- Nose-only inhalation exposure
- Whole body inhalation exposure
- Nasal dosing
- Intratracheal aerosol dosing

## STUDY TYPES

- Acute, subchronic and chronic inhalation toxicology
- Reproductive inhalation toxicology
- Carcinogenicity (traditional and transgenic)
- Efficacy studies in respiratory disease models
- Pulmonary sensitization
- Sensory irritation
- Lung inflammatory response
- Comprehensive IND- and NDA-enabling preclinical programs



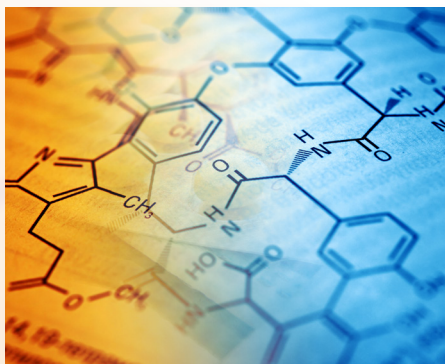
## THE IITRI ADVANTAGE

- Over 40 years of expertise in aerosol science and inhalation exposure
- Ability to aerosolize complex test samples including powders, fibers, nanoparticles, and chemicals
- Expertise and facilities to accommodate studies in both small and large animal models

# Inhalation Drug Development

Development programs for inhaled medications require a CRO partner with specialized expertise in test atmosphere development, inhalation pharmacokinetic (PK) studies, and GLP-compliant inhalation toxicology and safety studies. IITRI has extensive experience in preclinical safety evaluation of drugs delivered by the inhalation route to support submissions to the FDA, including:

- Inhaled asthma medications: ipratropium bromide lactose inhalation blend and Atrovent HFC 134A
- Inhalation formulations of antibiotics
- Inhaled anesthetics
- Inhalation studies using the metered dose inhaler device for aerosolization



## DRUG DISCOVERY

- EpiAirway *in vitro* PK screening
- Efficacy animal models for respiratory diseases
  - Asthma
  - COPD
  - Pulmonary fibrosis
  - Bacterial and viral infections
- Pharmacokinetics (PK) studies
- Bioavailability analysis

## GLP SAFETY AND TOXICOLOGY

- Repeat-dose toxicology studies
- Safety pharmacology
- Analytical chemistry
  - Bioanalytical services
  - Bioanalytical method validation
  - Sample analysis with TK modeling
  - Formulation optimization
- Genetic toxicology
- Reproductive toxicology
- Carcinogenicity studies

## CLINICAL TRIAL SUPPORT

- Bioanalytical method cross-validation
- Drug and metabolite analysis in biological matrices including tissues
- Pharmacokinetics (PK)
- Immunogenicity testing
- Modulation of cytokine expression
- Assessment of biomarkers
- Molecular biology analysis



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