TOXICOLOGY SERVICES

Frontage's toxicology group provides all of the resources you'll need for your investigational plans. Our team of study directors, technicians, and program managers will help guide you through the non-regulatory tolerability, dose-range finding, and acute toxicology studies to help set you up for success in your regulated program.

Non-GLP Studies

The non-GLP studies leading into the GLP toxicology program are important elements of a successful program. MTD studies, repeat-dose range finding studies, exploratory PK studies, etc. are commonly needed to justify the selected dose levels for the pivotal studies to follow.

A properly conducted preliminary package will lead to successful GLP studies by de-risking / removing less desirable compounds and allowing faster development of more appropriate lead candidates.

GLP Studies

Frontage GLP toxicology studies have supported hundreds of successful client IND submissions. All standard dosing regimens and species are supported, including primates, and our GLP toxicology studies are conducted in strict compliance with GLP and animal welfare regulations.

Our QA is managed on a global basis as 'Two Continents / One System' with common QA processes throughout the company – and with on-site QA teams embedded in each business unit.

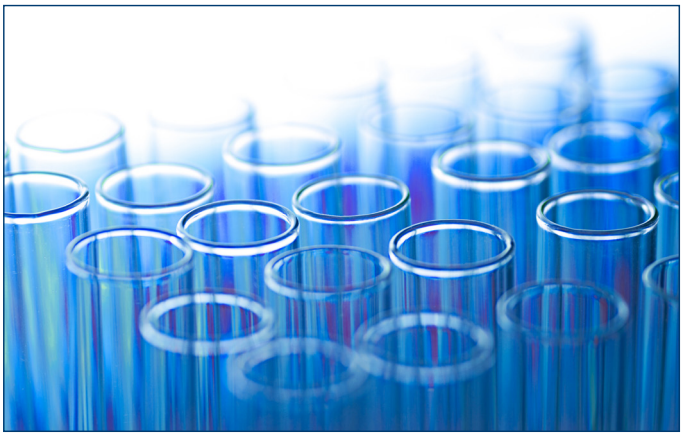
Pivotal Toxicology

We offer pivotal toxicology studies for safety and toxicity evaluation of candidate compounds. Our toxicological studies are conducted on a variety of animal models, ranging from IND-enabling to smaller tox studies, and provide a basis for identifying hazards and conducting safety assessments that support IND filing and support use in humans.

Our IND-enabling toxicology is performed by experienced scientists who can recommend appropriate study parameters and protocol elements, enabling the collection of a robust and comprehensive data package for IND submission. We offer comprehensive expertise to execute your IND study needs with services optimized to meet the most aggressive execution timelines.

FRONTAGE
YOUR DRUG DEVELOPMENT PARTNER

Toxicology Service Capabilities



Genetic Toxicology

- Bacterial Reverse Mutation Assay ('Ames' Assay)
- *in vitro* Micronucleus Assay
- *in vivo* Micronucleus Assay – rat or mouse

General Toxicology

- Tolerability studies
- Dose-Range Finding studies
- Acute to Subchronic to Chronic Toxicology studies
- Acute Neurotoxicology studies
- Acute Neurotoxicology studies

Routes of Administration

- Oral Gavage
- Oral Capsules, tablets, pills (non-rodent)
- Dietary admixture
- Intravenous
  - Bolus injection
  - Infusion
- Subcutaneous injection
- Intramuscular injection
- Dermal application
- Intraperitoneal injection
- Intranasal

Related Services for Toxicology Programs

- ADME services (metabolism, QWBA, more)
- On-site bioanalytical
- On-site formulation lab and formulation analysis
- Safety Pharmacology – respiratory, cardiovascular telemetry, and CNS
  - Stand-alone or embedded in pivotal tox programs
  - Infusion
- Program Management for integrated projects.

Frontage Laboratories, Inc. is a contract research organization (CRO) that provides integrated, science-driven, product development services throughout the drug discovery and development process to enable pharmaceutical and biotechnology companies to achieve their development goals. Comprehensive services include drug metabolism and pharmacokinetics, analytical testing and formulation development, preclinical and clinical trial material manufacturing, bioanalysis, preclinical safety and toxicology assessment and early phase clinical studies. Frontage has enabled many biotechnology companies and leading pharmaceutical companies of varying sizes to advance a myriad of molecules through development and file regulatory submissions in the United States, China, and other countries.

FOR MORE INFORMATION, CONTACT US AT: *sales@frontagelab.com* **OR VISIT US AT:** *frontagelab.com*

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