

# DRUG SAFETY SERVICES

## **EXPERIENCE.** From discovery to full development: Frontage has the know-how.

Frontage Laboratories provides drug safety services to guide new therapies from discovery to full development support. Our extensive profile of IND enabling pivotal studies support swift progression of your lead compounds into the clinic – streamlining your development process.

We provide the resources of a highly skilled, client-focused staff with extensive academic, scientific and pharmaceutical industry experience.

#### **DRUG SAFETY SERVICES**

#### IND-enabling studies

- Regulatory/general toxicity
  - Maximum tolerated dose
  - Dose range-finding 5-14 days
  - Single and repeat-dose GLP
  - Rodents, dogs, NHP, minipig
  - Complete bioanalytical support including small and large molecule analysis
  - Complete Toxicokinetics Support
- Safety pharmacology
  - ICH core battery: CV, CNS, respiratory
  - Supplemental studies: renal, GI
- Full clinical and anatomic pathology, ophthalmology, ECG

#### Post IND Service

- Chronic toxicity
- Juvenile toxicology (Rats)
- Investigative toxicology

#### **GLP** Analytical Support

- Dose formulation analysis method development, validation, sample analysis under GLP
- Bioanalytical method development, validation, sample analysis under GLP, plus pharmacokinetics determination





### **PARTNERSHIP**

#### It's what turns services into solutions

Frontage Laboratories employees have one goal in mind— to meet your next milestone on time with quality. We are always on the cutting edge of the evolving preclinical safety and metabolism field. Beyond the basics, we are adept at specialized and novel approaches.

#### FRONTAGE LABORATORIES ADVANTAGES

- Comprehensive toxicology services
- International recognition by AAALAC for commitment to animal welfare
- Specialized regulatory and scientific expertise
- Speed and flexibility
- Access to historical data

#### **CORE STRENGTHS**

- Scientific and regulatory expertise
- Direct access to scientists
- Rapid initiation and turnaround time
- Compliance with GLP regulations
- Low staff turnover
- AAALAC accreditation

Frontage Laboratories, Inc. is a CRO providing integrated, scientifically-driven research, analytical and development services throughout the drug discovery and development process to enable biopharmaceutical companies to achieve their drug development goals. We offer our clients comprehensive services in analytical testing and formulation development, drug metabolism and pharmacokinetics (DMPK), bioanalysis, preclinical safety and toxicology and early phase clinical studies. We have enabled many innovator, generic and consumer health companies of all sizes to file IND, NDA, ANDA, BLA and 505(b)(2) submissions in global markets allowing for successful development of important therapies and products for patients. We have successfully assisted clients to advance hundreds of molecules through development to commercial launch in global markets. We are committed to providing rigorous scientific expertise to ensure the highest quality and compliance.

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

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