



## Supporting Our Partners in Developing Life-Saving Treatments





Frontage is focused on helping clients to address their most significant and complex drug discovery and development challenges. Our deep scientific expertise, cutting-edge technologies, and reputation for high-quality services help us turn our services into your solutions.



This approach ensures that our clients receive the same high-quality standards, operating procedures, latest technologies and systems in both North America and China while providing a detailed and highly experienced understanding of the regulations and requirements for drug discovery and development in both countries.

- Well-established assay and material transfer process to support the global clinical trials

Our mission for over 20 years has been to help our partners in biopharmaceutical and life sciences make their goals a reality. As a fast-growing, full service CRO, we develop integrated solutions to drive drug development goals which, in turn, help those who need them most.

- Over 20 years of successful growth
- Double-digit revenue growth over the last 10 years
- >1,600 employees at 23 sites across 2 continents
- 80% of clients are repeat clients



• Integrated global resources for streamlined processes and shared platforms • Tailored solutions for your unique needs, delivering end-to-end success



## **Our Commitment to Your Success**

We have successfully assisted clients to advance hundreds of molecules through development to commercial launch in global markets. We focus on helping our clients address their most significant and complex drug discovery and development challenges.



## UNPARALLELED **EXPERTISE**

#### A cross-functional team of exceptionally talented scientists and qualified management

Frontage has the proven ability to deliver value-added technical expertise. We offer a large global team of scientists and managers to support the swift progression of our lead compounds into the clinic - streamlining our developmental process.

- 1,000+ scientists globally
- Able to understand and solve complex scientific challenges
- Majority of our scientists hold advanced degrees, including MS, PhD, or MDs
- · Scientists with expertise across a range of disciplines

## EMPHASIS ON DATA QUALITY AND INTEGRITY

Approaching every project from end to end to ensure only high-quality data Frontage is committed to providing rigorous scientific expertise assuring the highest quality and compliance for each project.

- GMP, GCP, and GLP compliant
- CLIA-certified and AALAC-accredited
- Stringent quality management systems
- Strong track record of regulatory inspections
- In-house quality control and quality assurance programs
- Same quality standards, operating procedures, setup and systems in China as in North America

## THE LATEST TECHNOLOGY

and development standards

Frontage consistently builds strategic investments in instrumentations, capacity, and capabilities that allow us to be a globally-renowned leading service provider. Our aim is for our facilities to remain at the forefront of the global pharmaceutical research and analytical and development standards.

- Over 1.2 million total square footage of laboratory space globally
- Enhanced capabilities and expertise through organic service development to meet client needs
- Strategic acquisitions designed to expand our portfolio of services and strengthen our value proposition to clients
- · Consistent investment in instrumentation and software

#### World-class facilities and equipment that remain at the forefront of global pharmaceutical research and analytical



Frontage collaborates closely with you - our partner - to tackle complex, scientific challenges and deliver critical solutions and quality results for your regulatory needs.



This is a representative grid. A more comprehensive list of services can be found on our website frontagelab.com.



Discovery Services



## Propelling Early Discoveries with Technical Excellence

Frontage's discovery team supports you in identifying and optimizing lead compounds and accelerating the developmental candidate's process, saving clients time and money at later stages of their journey.

- Experienced leadership team responsible for 20+ clinical compounds and multiple marketed therapeutics
- Extensive collaboration with 250+ organizations, including the largest biopharma and start-up biotech companies
- Timely and cost-effective support with SAR data to advance candidate selection

## Understanding and Solving Complex Scientific Challenges

Our experienced scientific team provides broad and indepth expertise on appropriate study designs, execution, and interpretation of data to support critical decisions in advancing potential therapeutic agents for further development.

#### Services:

- Medicinal Chemistry Services
- Compound Management
- Biology Services: SAR, Selectivity, MOA
- ADME Screening
- Discovery PK and Early Toxicology



DMPK Services



## **Proven Techniques and Best-in-Class Approach**

DMPK studies help provide you with critical decision-making data during the discovery and development of new chemical entities and compounds in development.

- 7 locations globally
- 30+ employees cross-trained with an average experience of 10-15 years
- Deliver complete data packages with analysis and interpretation

#### Services:

- In Vitro ADME screening and development studies
- In Vivo Studies
- Metabolite Syntheses
- QWBA and Radiolabel/Isotope Services
- Human Radiolabel Studies (hAME)

## **Bioanalytical Services**



## **Integrated Solutions for Complex** Scientific Challenges

Our large bioanalytical team across the globe is experienced in challenging projects and applications and seamlessly works together to support comprehensive, regulated quantitative analyses.

- Expertise in complex drug development processes
- Over 90 LC-MS/MS systems
- 500,000+ samples per year sample analysis capacity
- Single and multiplex analyses
- Ultra-sensitive detection capabilities (femtogram/mL)
- CLIA-certified laboratory

## Safety and Toxicology Services



## **Streamlining your Development Process**

Our comprehensive services are aimed at preparing your product for the NDA stage. We collect a robust and comprehensive data package to identify the pharmacological and toxicological effects of your drug candidate.

- GLP and non-GLP services
- ~100,000 square feet of vivarium/ laboratories
- In-house clinical pathology, histology, pharmacy
- AAALAC Accreditation
- Integrated chemistry and biology services to accelerate your program

#### **Services:**

- General Toxicology
- IND-Enabling Services
- Genetic Toxicology
- DART
- Safety Pharmacology

## CMC **Services**



Frontage's broad portfolio of CMC services spans drug product development, analysis, and clinical trial materials' delivery and supply from preclinical stages through Phase II clinical trials.

- DEA License for handling Controlled Substances, Schedules 1-5
- US FDA, Canada FDA, and EU QP inspected facility and quality system
- 2,000+ test methods developed and validated
- to patients for clinical trials

#### Services:

- Small Molecules with LC-MS/MS
- Biologics (ADC, Mab, Proteins, Peptides, PK, Immunogenicity)
- Biomarker Services (Comprehensive Assay Platforms)
- Genomics Services

## **Committed to Quality and Compliance**

- 90% of the clients are repeat clients

• 600+ GMP batches prepared and sent

#### Services:

- Analytical Services for Small and Large Molecules
- Formulation Development
- Clinical Trial Materials (CTM) Manufacturing
- Microbiological Testing
- API Synthesis
- Commercial product release and stability testing



Clinical **Services** 



## **Advancing Your Investigative Compound** to a Drug Candidate

Frontage's Clinical Services team has over 25 years of experience in partnering closely with each client to develop a unique approach to overcome the challenges of each study while maximizing efficiency and mitigating risk.

- Clinical services in China and U.S. have 1,000+ beds
- 1 U.S. Clinic and 4 Clinical Centers in China
- Experience in broad range of study types and delivery systems

#### Services:

- Phase I and IIa studies
- Specialty studies include FIH, tobacco, and hAME
- Data Management, Biometrics, and Medical Writing

## **Managing Your Project** Experience the Confidence of a Reliable Partnership

To ensure a successful project, the Frontage teams collaborate with you, our partners, to scope out your project in phases. Everything from defining clear objectives and drafting protocols, to establishing milestones and managing the critical resources, are carefully laid out within the plan. Our special workflow is optimized for transparency and clear communication with you, incorporating quality, compliance, and CAPA, to deliver projects on time and within budget.

# THE FRONTAGE APPROACH



## Central Laboratory and Testing



## Supporting You with Next-Generation Systems

Frontage's full suite of services under central laboratories gives clients access to the next generation central lab services.

- CLIA Certified
- 100% Client Retention
- 30+ clients, including top clinical CROs
- Capability for handling high testing volume each day
- Site-to-site data harmonization
- Operational agility and workload fluidity to meet urgent timelines

#### Services:

- Biorepository Service
- Project Management and Logistics
- Routine Lab Testing Services
- Histology and Pathology Services

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



# **PRONTAGE**

#### **GLOBAL OPERATIONS**

DISCOVERY:	
North America – Hayward, CA   Palo Alto, CA	China – Shanghai   Wuhan   Weihai
DMPK:	
North America – Exton, PA   Vancouver, CN   Monmouth Junction, NJ   Hayward, CA   Concord, OH	China – Shanghai   Suzhou
SAFETY AND TOXICOLOGY:	
North America – Concord, OH   Chicago, IL	China – Suzhou
BIOANALYTICAL AND GENOMICS:	
North America – Exton, PA   Hayward, CA   Deerfield Beach, FL   Vancouver, CN	China – Shanghai   Suzhou   Wuhan
PRODUCT DEVELOPMENT:	
North America – Hayward, CA   Palo Alto, CA	China – Shanghai   Suzhou   Yantai
EARLY CLINICAL:	
North America – Secaucus, NJ	China – Zhengzhou
CENTRAL LAB:	
North America – Exton, PA	China – Shanghai