

# PARTNERSHIP

It's what turns services into solutions.



## CMC (CHEMISTRY, MANUFACTURING, AND CONTROL) GMP ANALYTICAL TESTING FOR NEW CHEMICAL ENTITIES AND COMMERCIAL PRODUCT SUPPORT

**QUALITY.** *It's how you get from formulation to the pharmacy.*

Ensure comprehensive product analysis with Frontage's team of experienced analytical scientists.

WE HAVE AN  
UNPARALLELED  
COMPLIANCE AND  
QUALITY TRACK  
RECORD

We specialize in analytical method development, validation and transfer for product development and clinical trial materials (CTM) manufacturing support, as well as commercial product release and stability testing. Our services are designed to help sponsors throughout the drug development process in their effort to fully characterize drug substances, developmental formulations and commercial drug products.

Our facilities house a wide range of the latest analytical instrumentation for a comprehensive array of methods. And, we continually keep pace with technology to ensure compliance with evolving regulatory and market requirements.

## ANALYTICAL SERVICES

- Analytical method development, validation and transfer

- Stability testing and storage (all ICH conditions)
- In-vitro bioequivalence and dissolution / diffusion IVRT and IVPT evaluations
- API and finished product testing
- Unknown impurity identification
- Comparator product analysis / reverse engineering
- Extractable and leachable studies

## COMPREHENSIVE CMC SERVICES

- Drug product development and CTM manufacturing of liquid, semi-solid, oral solid, and sterile dosage forms
- Formulation development in supporting IND, NDA, ANDA and consumer products
- Specialized services for high potency, controlled release, DEA regulated, and sterile products
- API development and GMP manufacturing
- Impurity isolation/identification/synthesis
- Reference standard synthesis

## EXPERIENCE

Frontage brings experience in analyzing a variety of dosage forms including oral solid, liquid, lyophilized, topical, liposomes / emulsions / suspensions and other products.

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Our chemists' expertise includes chromatography, dissolution/diffusion testing, UPLC, HPLC/MS, UPLC/MS, GC/MS, IC, ICP/MS, Karl-Fisher and titrimetric methods, among others.

## STABILITY MANAGEMENT SERVICES

Frontage offers a variety of storage conditions for test samples to meet the demands of drug development requirements in different markets throughout the world. We have the scale of equipment to handle large studies and specialized studies alike.

- Six walk-in stability chamber rooms for standard storage conditions (25 °C/60%RH, 30 °C/65%RH, 40 °C/75%RH) - approximately
- 4,000 total cubic feet of capacity Reach-in chambers (-70 °C, -20 °C, 25 °C/40%RH, 40 °C/NMT 25%RH, 30 °C/75%RH) for special container requirements and complex products
- Photo-stability chamber meeting ICH accelerated light exposure study requirements

## QUALITY ASSURED

With an excellent compliance history, Frontage operates under strict adherence to ICH and US FDA GMP guidelines. Our facilities and processes undergo routine audits and inspections from sponsors and regulatory authorities. Our SOPs, while robust, have the flexibility to accommodate a variety of protocols, templates and reporting formats according to client requirements and preferences.

## FRONTAGE'S COMMITMENT

For many sponsors who rely on service partners to help develop and commercialize their products, good science is not enough. For more than 10 years, Frontage has earned a reputation for collaboration, responsiveness and the ability to customize service and deliverables that are aligned with the needs of our clients.

*Frontage is a full service CRO which closely collaborates with pharmaceutical and biotech companies to help them bring promising drug candidates to market.*

*We offer solutions to help our clients in analytical testing, product development, DMPK, bioanalysis, clinical, and biometrics. What sets us apart is our ability to collaborate closely with our clients to ensure a deep understanding of their drug development goals and our ability provide flexible solutions that are customized to each client's needs.*

*At Frontage, we are committed to providing rigorous scientific expertise to ensure the highest quality and compliance on each project. Frontage proudly serves innovator, generic and consumer health companies from IND enabling through late stage clinical projects. Frontage successfully assists clients to advance hundreds of molecules through development to commercial launch in global markets. This partnership with our clients is how we turn services into real solutions that get our clients ahead.*

**FOR MORE INFORMATION, CONTACT US AT:** [sales@frontagelab.com](mailto:sales@frontagelab.com) **OR VISIT US AT:** [frontagelab.com](http://frontagelab.com)

### Headquarters, Bioanalytical and DMPK Services

700 Pennsylvania Drive  
Exton, PA 19341

**P: +1 610.232.0100**

**F: +1 610.232.0101**

### GMP Manufacturing and CMC Services

75 East Uwchlan Ave.  
Suite 100  
Exton, PA 19341

### Clinical Services

200 Meadowlands Parkway  
Secaucus, NJ 07094

### Biometrics

100 Franklin Square Dr.  
Suite 305  
Somerset, NJ 08873

