

# PARTNERSHIP

It's what turns services into solutions.



## CMC (CHEMISTRY, MANUFACTURING, AND CONTROL) PRODUCT DEVELOPMENT

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

Frontage's CMC portfolio of services spans drug product development, analysis, delivery and supply, from proof-of-concept, preclinical stages through Phase III clinical trials and commercialization support. With proven success in developing drug products for novel, generic and consumer products, we focus our efforts on clients' specific needs. Our formulation development experience and capabilities cover a wide range of dosage forms at IND, NDA, ANDA and 505(b)(2) project stages and applications.

WE HAVE AN  
UNPARALLELED  
COMPLIANCE AND  
QUALITY TRACK  
RECORD

## PRECLINICAL SUPPORT

Starting with a lead molecular candidate, Frontage performs a series of pre-formulation experiments to verify the physico-chemical properties of the candidate using evaluations of pKa, pH solubility / stability, excipient compatibility and crystal structure / physical evaluations. We can then determine an appropriate formulation to support good laboratory practice (GLP) studies and manufacture GLP study supplies.

## NEW CHEMICAL ENTITIES

For novel compound development, we start with an evaluation of our client's therapeutic target, desired exposure levels, available pharmacokinetic data, and active pharmaceutical ingredient characterization. Formulation development and stability studies are then rationally designed to obtain prototypes for preclinical and clinical evaluation by building quality and manufacturability into the process.

Our formulation development team has hands-on experience necessary to scale up prototypes for:

- Small and large molecules
- Including therapeutic proteins
- Pre-formulation screening
- Early phase and first-in-human
- Formulations
- Solubility enhancement
- API-in-bottles and API-in-capsules
- Blend-in-bottles and blend-incapsules
- Liquid-filled capsules
- Placebo matching
- Oral solids and liquids and suspensions
- Steriles and lyophilized

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- Lipid-based formulations and microfluidized emulsions
- Topical gels, creams and ointments

## GENERIC DEVELOPMENT

Frontage's team has successfully developed bioequivalent products for abbreviated new drug applications (ANDA) of lyophilized, injectable, ophthalmic, semisolid and modified release oral solid dosage forms. Our services begin with reverse engineering of the reference listed drug, followed by formulation development and optimization using Quality by Design principles, and finally, technical transfer to the sponsor's manufacturing facility. We also provide on-site, "man-in-the-plant" support for scale-up efforts.

## REGULATORY EXPERTISE

Frontage has both the resources and the expert staff to deliver long-term value for product registrations and communications. Bringing a deep knowledge of global health authority requirements, we offer comprehensive product development strategies for several markets, and assure the proper scale, conditions and documentation for regulatory filings.

## 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 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](mailto:sales@frontagelab.com) **OR VISIT US AT:** [frontagelab.com](http://frontagelab.com)

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