PARTNERSHIP

It's what turns services into solutions.

CMC (CHEMISTRY, MANUFACTURING, AND CONTROL) CTM MANUFACTURING

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

For early phase clinical trial materials, choose a product development team focused on scalability and performance. Ensure comprehensive product analysis with Frontage's team of experienced analytical scientists.

WE HAVE AN UNPARALLELED ***COMPLIANCE AND QUALITY TRACK RECORD***

Frontage brings a team of leading development scientists with hands-on experience in designing formulation, finished product and manufacturing processes. We have the equipment needed to model processes on the bench and pilot scales for technology transfer to large-scale manufacturing. We complement these capabilities with our good manufacturing practices (GMP) clinical trial materials (CTM) manufacturing areas for preclinical, Phase I and II clinical supplies.

FORMULATIONS

Frontage's formulation development and CTM manufacturing team designs formulations targeted for delivery of a therapeutic and then develops GMP manufacturing processes to ensure a high quality product is produced for clinical trials. We develop finished products supporting IND, NDA filings and generic ANDA filings. Our facilities have been designed for flexibility, as we offer a variety of dosage forms and the ability to handle highly potent compounds and DEA-controlled substances.

QUALITY ASSURED

Frontage knows that quality is the key to any successful project, bringing a solid track record of quality assurance and regulatory compliance. We have a successful inspection track record with US FDA, EU Qualified Persons, China FDA, and routine client audits, confirming our GMP capabilities and systems.

MANUFACTURING SERVICES – NOVEL DRUG, GENERIC EQUIVALENT AND CONSUMER HEALTH PRODUCTS

- Stability evaluation of prototype formulations in select container closure systems for lead formulation and commercial stability program management.
- Formulation development followed by process optimization studies for scale-up batch manufacturing incorporating Quality by Design principles
- Prototype manufacturing
- Regulatory-ready documentation (eCTD format)

FRONTAGE
YOUR DRUG DEVELOPMENT PARTNER

PARTNERSHIP

It's what turns services into solutions.

SPECIALIZED CAPABILITIES

- Potent compound handling for occupational exposure levels down to 1µg/m3 (or Safebridge category III)
- DEA licenses for analytical testing and manufacturing (schedules I-V for analytical and manufacturing)

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 18 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.

DOSAGE FORM	BATCH SIZE	PRODUCT TYPE
Oral Solid	0.5Kg – 30Kg	- Neat API fill in capsules and vials - Tablets: IR, modified release, osmotic bilayer, mini tablets and tablet-in-tablet - Capsules: modified release pellets and powders (with multiple populations) - Solubility enhancement
Sterile	500mL – 20L	- Aseptically-filled, stoppered vials using disposable mixing and filling technology - Ophthalmic solutions, emulsions and suspensions in 3-piece PE bottles - Lyophilized powder for injection
Semi-solid	0.5 – 100 Kg	- Creams, ointments, gels and lotions - Oral solutions and suspensions
High Potency	Up to 10Kg	- Neat API fill in capsules and bottles - Oral solid / Semi-solid / Liquid compounding

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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