PARTNERSHIP

It's what turns services into solutions.

CMC (CHEMISTRY, MANUFACTURING, AND CONTROL) CGMP ANALYTICAL TESTING FOR BIOLOGICS

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

Biologics or biopharmaceuticals are inherently more complex than small-molecule drugs. You need the right team to help you. Frontage has expertise and state of the art instrumentation necessary for the analytical method development, validation and transfer for complex biopharmaceutical compounds. Using bottom up, middle up/down, and top down approaches, we offer analytical support for characterization of primary, secondary and tertiary structures, post translational modifications such as glycosylation, disulfide linkage, antibody drug conjugation, or PEGylation.

COMPREHENSIVE SERVICES

- Release
- Stability
- Reference standard qualification
- In-depth structural elucidation
- Comparability or Biosimilarity
- Forced degradation
- Support of formulation development

ANALYTICAL METHODS FOR BIOLOGICS

- UV A280
- Peptide mapping by CE-MS/MS, LC-MS/MS
- Western Blotting
- Receptor Binding by ELISA
- Receptor Binding kinetics by SPR
- Intact mass by CE-MS, LC-MS
- Free thiol
- Secondary structure by UV CD
- Thermogram melting point by DSC
- Glycan profile by RapiFluor LC-Fluor/MS
- Drug antibody ratio by CE-MS/MS, LC-MS/MS
- HMW & LMW species by SEC HPLC
- Size by CE-SDS
- Charged Variant by cIEF, IEX
- Product purity by RP-HPLC
- Host Cell Proteins by ELISA, CE-MS/MS, LC-MS/MS
- Host Cell DNA by qPCR
- Process residuals by LC-MS/MS
- Endotoxin by LAL
- Sub-visible Particles
- Cell based assays

FRONTAGE
YOUR DRUG DEVELOPMENT PARTNER

PARTNERSHIP

It's what turns services into solutions.

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 expertise and equipment to handle large scale studies and specialized studies alike.

- Ten walk-in stability chamber rooms for standard storage conditions (5°C/60%RH, 30°C/65%RH, 40°C/75%RH)
- 10,000 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 stressed light exposure study requirements

QUALITY ASSURED

With an excellent compliance history, Frontage operates under strict adherence to ICH and US FDA CGMP 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.

THE FRONTAGE 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* **OR VISIT US AT:** *frontagelab.com*

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