

We Turn Services into Solutions



Two Countries, One System





Shanghai, S

CMC Services

• Suzhou

Clinical operati

Zhengzhou





Strong Scientific and Management Expertise

Highly educated and experienced employee base

Broad and Integrated Product Development Services

Drug product development services spanning from late Discovery through Clinical Development, supporting regulatory filings and postmarketing

State of the Art Equipment and Facilities

Over \$40 MM invested in instruments, equipment and facilities enabling end-to-end drug product development R&D support

Our Quality System; "Two Countries, One System"

Highly successful inspection record by US FDA, CFDA, WHO of regulated work in both the U.S. and China, effectively operating as a bridge between the U.S. and China

Our Purpose

To improve quality of life

Our Vision

To be the preferred partner of life science leaders in product development



Our Values

Quality

We are committed to excellence in the results we achieve, and how we achieve them.

Integrity

We believe in honesty, reliability and accountability in our words and behavior.

Innovation

We employ new scientific approaches, technologies and processes to provide innovative solutions to challenging problems.

Caring

We care for our patients, customers, employees, stakeholders, communities and environment.

Integrated, Analytical and Scientifically-Driven Research and Development Services



Our Services in Each Stage of The Drug Discovery and Development Process

Drug Discovery	>	Pre-Clinical Development	>	Clinical Trials (Phases I-III)	>	Post Approval (Phase IV)		
DMPK								
 PK screening and characterization PK/PD studies 	•	In vitro and in vivo ADME Metabolite ID / Profiling in difference species	:	Mass balance studies Metabolites in safety testing Drug-drug interaction studies				
Safety and Toxicology								
 Immunosafety testing Pharmacology assessment 		Regulatory / general toxicity studies Pathology, ophthalmology and Cardiovascular safety First-in-human IND application support Non-GLP and GLP toxicology studies	:	Chronic toxicity studies Investigative toxicology Carcinogenicity studies Toxicology support for additional indications	5			
Bioanalytical								
 Immunogenicity assessments Cell based Non-cell based Non-cell based Non-GLP research based assays Liquid chromatography and mass spectrometry Ligand binding 								
Chemistry, Manufacturing and Controls ("CMC	<i>:")</i>							
 Lead compound qualification Analytical testing 	:	Formulation development Analytical testing <i>In vitro</i> release and product testing GLP toxicology batch manufacturing Stability testing and storage	:	CTM/GMP manufacturing Stability testing and storage Extractability studies Impurity identification		Commercial product release and stability testing		

Clinical Services

- Clinical Study Design and Execution
 - Data Management and Biometrics
- Medical Writing and Regulatory Support

Highly experienced and professional management team

Highly Experienced Senior Management Team





Frontage Laboratories, Inc., has been awarded the Healthcare CEO award from Philadelphia Alliance for Capital and Technologies, Ernst & Young Entrepreneur of the Year Award. Dr. Li received his Ph.D. in Analytical Chemistry from McGill University in Canada



Dr. Zhang over 15 years experience in drug analysis; published over 60 papers and reports. He received his Ph.D. degree in analytical chemistry from the University of Florida







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United States Based Services





DMPK



SAFETY & TOXICOLOGY

BIOANALYTICAL

- Biomarker Services
 Preclinical and Clinical Support
- Global Bioanalytical Services (65+ LC-MS/MS)
- Biologics Assay (Antibody Drug, ADC, Oligonucleotide)





CLINICAL

BE, Food Effect, DDI

• First to File Packages



BIOMETRICS

- CDISC-Compliant Datasets
- Biostats and SAS Programming
- Preclinical-Phase IV
- Development Support
- EDC & Data Management

- Rapid PK; In Vitro
 ADME
- Mass Balance
- Early Discovery to Late Development
- Metabolite
 Identification

toxicity
Safety pharmacology
Full clinical and anatomic pathology,

• IND Enabling Studies

• Regulatory/general

- ophthalmology, ECG
- Post IND Service
- GLP Analytical Support

Analytical ServicesFormulationClinical Centers in US and China

- Development
 CTM Manufacturing
 Phase I: SAD, MAD, BA,
 DE Food Effect, DDI
- GMP commercial
- stability
- Small molecules & Biologics
- IND & ANDA

China Based Services







Bioanalytical

- >50,000 sqf facilities located in Shanghai and Suzhou
- >150 Scientists; >70% have advanced degrees
- 30 LC/MS/MS with WatsonLIMS system
- US-China method cross transfer and validation abilities
- Support sample analysis for small molecules drugs and biologics

CMC/CTM

- >30,000 sqf facilities located in Suzhou
- >70 Scientists; >70% have advanced degrees
- Analytical method dev/val; stability and release testing
- Formulation development – various dosage forms
- Clinical trial material manufacturing

Clinical

- 18 Hospital-based early phase clinical centers in different regions
- >1,000 beds capacity
- >70 Clinical research Scientists
- Various therapeutic area experience
- DM/BioStat fully support functions
- Late phase clinical trial capabilities

State of the Art Equipment and Facilities

- ~100 LC-MS/MS available for small and large molecule analysis
- Frontage was first to offer ultra-sensitive biomarker quantification with Quanterix Simoa[™]
- Magpix Luminex and Ella Protein Simple instrument platforms enables efficient screening of multiple biomarkers and isolation of a single critical biomarker candidate from a large pool of analytes
- **Culex System** promotes reduction of animal usage by serial bleeding of mice for pharmacokinetic studies
- **Maurice System** enables separation of charge/size variants in a stable pH gradient established by ampholytes in a capillary, and detection by whole column imaging with UV absorbance or native fluorescence
- **160-bed phase I clinic** located less than 7 miles from NYC, with access to a large diverse population of volunteers
- 18 co-developed clinical centers with more than 1,000 beds



Unparalleled Compliance and Quality Record



Frontage US FDA Inspections (2000-2018)

- Our facilities and processes undergo routine audits and inspections from sponsors and regulatory authorities, including US EPA, US FDA, Health Canada, WHO
- Operates under strict adherence to ICH and US FDA GMP guidelines
- Compliant with internal standard operating procedures (SOP), Good Laboratory Practice (GLP) and world health authority guidance.
- CLIA Certified Laboratory
- AAALAC Accredited
- OLAW Assurance



Service Area (Location)	# Inspections	Inspection Year/s
BIO-US/ CMC-US (HQ, Exton, PA)	12/2	2004-2018
CMC-US (Exton, PA)	8	2006-2017
FCS-US (Hackensack, NJ)	7	2009-2014
FCS-US (Secaucus, NJ)	3	2016-2018
Drug Safety and Metabolism (DSM)-US (Concord, OH)	13	2000-2018
BIO-CH/ CMC-CH (CH HQ, Shanghai, China)	2/1	2013
CRC-CH (Zhengzhou, China)	1	2013
CRC-CH (Changchun, China)	1	2015
CMC-CH (Suzhou, China)	1	2016
Total US FDA Inspections (US AND CHINA)	51	2000-2018



Agency	Service Area (Location)	# of Inspection/s	Inspection Year/s
ANVISA (Brazil)	BIO-US (HQ Exton, PA)	1	2018
DEA	BIO-DMPK-US (HQ Exton, PA)	1	2014
DEA	Drug Safety and Metabolism (DSM) (Concord, OH)	3	2016-2018
DEA	CMC-US (Exton, PA)	1	2016
DEA	FCS (Secaucus, NJ)	2	2015-2016
EPA	BIO-DMPK-US (HQ Exton, PA)	1	2015
EPA	Drug Safety and Metabolism (DSM) (Concord, OH)	6	2000-2018
Health Canada	CMC-US (Exton, PA)	1	2016
WHO	BIO-CH (Shanghai, China)	1	2013
WHO	CRO-CH (Beijing, China)	1	2013
WHO	CRC-CH (Zhengzhou, China)	1	2013



Service Overview









Technical Expertise

- 25+ employees; cross-trained
- Avg experience 10-15 years
- Ability to provide scientific input to designs and interpretation of data to influence decisionmaking process

Automation for Increased Precision and Efficiency

- Advanced automation instrumentation for in vivo ADME, in vitro ADME
- Our current liquid handling platforms include Tecan and Tomtec
- Automation for in vivo PK studies minimizes animal usage/handling and accelerates study timelines while maintaining high-quality data.

Rigorous Quality

- Standard operating procedures (SOPs)
- Watson LIMS for sample inventory management
- Temperature controls and ultra-low temperature freezers help preserve data quality and specimen integrity
- All studies are conducted in accordance FDA and EPA GLP, IACUC protocols, Nuclear Regulatory Commission and the Pennsylvania Bureau of Radiation Protection Regulations for radioactive materials.

Safety & Toxicology







Specialized Facilities

- Compliance with GLP regulations
- AAALAC accreditation
- DEA licensed facility, regular inspections with all major regulatory bodies, excellent regulatory track record and reputation
- 43 animal rooms
- Provantis (wireless data collection, 21 CFR 11 compliant)
- Microchip animal identification

Scientific Expertise

- Integrated program management oversight
- Board-Certified Toxicologists, Veterinarians and Pathologists
- Experienced study directors and detail-oriented technicians
- Rigorous quality management process embedded throughout the entire organization and process

Speed and Flexibility

- Rapid project initiation
- Fast turnaround time
- Integrated chemistry and biology services to accelerate your program
- Full support labs (clinical pathology, histology, pharmacy) under one roof

Bioanalytical Services







17 Years of Strong Scientific Expertise

- 70% of staff have advanced degrees
- Senior scientists average 10 15 years in complex drug development
- Many come from leading pharmaceutical companies
- Small molecule, biologics and biomarkers expertise

Outstanding Quality and Compliance

- Outstanding audit history with more than 30 inspections by the FDA, WHO and Health Canada.
- Compliant with internal standard operating procedures (SOP), Good Laboratory Practice (GLP) and world health authority guidance.
- CLIA Certified Laboratory

Wide Range of Technology Platforms

- High Capacity with over 65 LC/MS/MS
- 200,000 -500,000+ Samples (Annual Capacity)
- Multiple Immunoassay platforms
- Ultra-sensitive detection capabilities (femtogram/mL)
- Single and multiplex analysis in various disease categories

CMC (Chemistry, Manufacturing and Control) Services





Capacity & Expertise

- Over 1,500 Methods Method Dev/Method Validation/Method Transfer
- 220 Clients -- 220 Compounds -- >450 GMP Batches

Outstanding Quality and Compliance

- Our facilities and processes undergo routine audits and inspections from sponsors and regulatory authorities. including US EPA, US FDA, Health Canada, WHO
- Operates under strict adherence to ICH and US FDA GMP guidelines
- Seven (7) FDA inspections in past 8 years: no 483 for lab operations
- Inspected by Health Canada & European Union Qualified Person (EUQP)



Designed to Provide Flexibility

- Facilities engineered to offer a variety of dosage forms
- OSD, Topical, Sterile Solution & Lyo powder
- Ability to handle highly potent compounds and DEA-controlled substances

Clinical Services







Over 20 years of Early Stage Clinical Experience

- Experience in execution of comprehensive Phase I-IIa studies
- Experience in broad range of study types
- Expertise in wide variety of delivery systems

Purpose-Built Facility

- Modern 36,000 sq. ft. facility
- Multiple units with 160 beds
- Secure limited-access pharmacy
- Video monitoring and key card access
- Rees monitoring on freezers
- Back-up generator

Prime Geographic Location

- Less than 7 miles from NYC
- Access to over 29.5 million potential volunteers
- Proximity to extensive mass transit and 2 major airports
- Located near some of the leading medical facilities in the country
- 0.25 miles to local ER



Biometrics







Extensive Experience

- Biostatistics consultation and analyses by staff statisticians with more than 20 years of industry experience
- Expertise in generation of CDISC-compliant datasets and supporting documents
- Phase I-III and post-marketing study support



- Clinical development plans and study designs
- Medical writing including protocol, ICF, SAP, DMP, and CSR
- Full Data Management services
- Sample size estimations, randomization schedules and TLFs
- Pharmacokinetic consultation and analyses

Service Integration

- Stand alone biometric services or fully integrated with Phase I clinic
- Dedicated Project Manager assigned to each project
- Focus on communication









Appendix

Our Strengths and Growth Strategies

Our Strengths



Well positioned in the world's two largest pharmaceutical markets



Proven ability to deliver value-add technical expertise



Effective quality management systems and strong track record of regulatory inspections



Diverse and growing customer base with increasing customer retention



Strong track record of efficiency and flexibility



Highly experienced and professional management team

Our Growth Strategies



Expand Capacities to Capture Market Growth



Expand Services to Provide Integrated Solutions



Capitalize on the Chinese Market Growth



Attract and Retain Top Talent



Maintain, Deepen, and Expand Customer Base