



# DRUG DEVELOPMENT AND REGULATORY CONSULTING



## Comprehensive Knowledge

## Successful Track Record

## Experienced Team

Frontage Drug Development and Regulatory Consulting Group facilitates the strategy, planning and implementation of your drug development programs and regulatory submissions. The key consulting areas include:

- Consulting Services in:
  - Clinical Pharmacology
  - Chemistry, Manufacturing and Controls (CMC)
  - Pharmacology and Toxicology
- Regulatory Filings (INDs, NDAs and ANDAs) with eCTD templates and Regulatory Project Management
- FDA Communications including Agent Representation, Meeting Management and Liaison Activities

Our experienced consulting group is led by a former FDA senior Clinical Pharmacology Reviewer with extensive drug development and regulatory approval experiences (6 years in CDER/FDA and 6 years in pharmaceutical industry).

### For more information, contact:

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## Recent Case Studies Exemplifying our track record of quality service

- **Successful** completion of the clinical pharmacology and biopharmaceutics sections of an NDA for a pharmaceutical company in Europe
- Provided clinical pharmacology and regulatory consulting for a specialized U.S. pharmaceutical company
  - Contributed to discussions with the FDA review division to waive a TQT study for an NDA
  - Contributed to the preparation of meeting package and discussions at an EOP2 FDA meeting
- Ongoing work with two major Chinese pharmaceutical companies for their respective **first NME drug development in the United States**
  - Including consulting for the IND preparation (CMC, Pharmtox and clinical protocols), U.S. FDA interactions from pre-IND meeting, IND filing and clinical development programs
- **Recent ANDA approval** of Amlodipine Besylate for Beijing Second Pharmaceutical Co., Ltd. - Frontage was responsible for CMC development, bioequivalence studies, GMP Consulting, Facility Qualification, Quality System development, and regulatory filing for this ANDA project
- Ongoing work with a startup biotech company in U.S. on its **first biosimilar drug product indented for FDA submission**

## Frontage is a US-based global CRO with a full range of services for every stage of drug development

Our experience conducting fully integrated services gives us the unique ability to provide consulting for every phase of your project. No matter what stage of development your project is in, our experienced staff can provide knowledgeable insight and help.

The main areas of Drug Development and Regulatory Consulting include, but are not limited to, the areas listed below.

### Clinical Pharmacology

- Scientific and regulatory consultation on clinical pharmacology and biopharmaceutics portion of the drug development and registration plans
- Development clinical pharmacology strategies/plans based on preclinical packages, overall clinical development plans, current scientific knowledge, and applicable regulatory requirements;
- Identify and address clinical pharmacology and biopharmaceutics requirements/issues for drug development and approval
- Contribute to clinical pharmacology and biopharmaceutics portions of regulatory submissions
- Contribute to clinical pharmacology study protocol development, data analysis and study result interpretation
- Represent clients for communications with the FDA on clinical pharmacology and biopharmaceutical issues

The Clinical Pharmacology and Biopharmaceutics information includes but is not limited to:

- Pharmacokinetics (PK)
- Pharmacodynamics (PD)
- Exposure-response (PK/PD) relationships, Dose finding/selection
- Proof-of concept
- Intrinsic factors such as demographics, pharmacogenomics, renal and hepatic impairment, and disease states
- Extrinsic factors such as drug-drug interactions and food effects
- Bioavailability and bioequivalence (BA/BE) studies

### Interacting with State FDA (SFDA) of China

- Provide regulatory guidance to clients on their clinical trial applications and drug registration to SFDA;
- SFDA communications including Agent Representation, Meeting Management and Liaison Activities;
- Regulatory filings for new drug applications (e.g., CTA and CPP);
- Import drug registrations (e.g., IDL, CPP)

### Pharmacology and Toxicology

- Provide scientific and regulatory guidance to clients on the Pharm Tox portions of the drug development and registration plans
- Develop Pharm Tox strategies/plans for clients, based on detailed analysis of overall clinical development plans, and current knowledge of science and applicable regulations
- Identify and address Pharm Tox requirements/issues for drug development and approval
- Contribute to the study protocol design, data interpretation and review of study reports
- Contribute to Pharm Tox portions of regulatory submissions;
- Represent clients to communicate with the FDA with regard to Pharm Tox issues

### Chemistry, Manufacturing & Controls (CMC)

- Provide scientific and regulatory consultation on the required development studies that determine the critical quality attributes of the drug substance, drug product and manufacturing processes at various stages of drug development and registration plans
- Develop strategies/plans for addressing FDA regulatory review questions on CMC portions of the application, including development of experimental plans to generate the required data for submission and authoring responses
- Identify and address CMC requirements/issues for drug development and approval
- Contribute to CMC portions of regulatory submissions
- Represent clients for communications with the FDA on CMC issues
- DMF filing support



Ask about our services in China  
In addition to our North American facilities, Frontage has a range of capabilities in Shanghai and Beijing.