

Frontage Laboratories, Inc. is one of the fastest growing collaborative R&D companies dedicated to advancing the development efforts of pharmaceutical companies around the world with our expertise in Preclinical, Clinical Pharmacology, CMC services (including formulation development, pharmaceutical analysis and clinical trial supply), Clinical Phase 1/2a, and Bioanalytical services. We specialize in assisting our partners to resolve complex product development challenges through our integrated services and divisions located in the United States and China.

JOB DESCRIPTION

Regulatory CMC Specialist/Manager

Frontage Laboratories is looking for a Regulatory CMC Specialist/Manager in our Drug Development and Regulatory Consulting Group. This individual is expected to have strong knowledge in the regulatory requirements at various stages of drug development for CMC sections of CTD formatted applications and excellent scientific writing skills. This individual will be responsible for preparing, reviewing, and compiling CMC sections of regulatory applications including investigational (IND) and marketing (ANDA and NDA) applications, amendments, supplements, annual reports, and drug master files.

Responsibilities:

- Drive all CMC submission activities (IND, NDA, and ANDA) including obtaining data and information from various client sites and research laboratories, writing/compiling the Module 2 Quality Summary and Module 3 textual body regulatory sections and evaluating/ensuring final versions comply with regulatory requirements;
- Summarize, tabulate, and format technical information (CMC) per regulations/guidelines to support regulatory applications;
- Participate in CMC drug development and regulatory consultation on clients' drug development projects and regulatory filing plans;
- Participate in communications with the FDA on CMC issues.

JOB REQUIREMENTS

- Minimum of 5 years experience in Regulatory Affairs and CMC area within the pharmaceutical industry;
- Solid working knowledge of drug development process and strong knowledge of FDA CMC regulatory requirements;
- Outstanding interpersonal and communication skills (both written and verbal);
- Minimum of a Bachelor's Degree in Chemistry, Pharmaceutics, or related fields.

OTHER

As a member of the Frontage team, you'll find an environment that celebrates diversity and encourages the open exchange of ideas. We are proud to offer an attractive salary along with a generous benefits package designed to support the needs of you and your family while addressing work/life issues. To learn more about Frontage Laboratories, Inc. or to apply online, please visit our website at www.frontagelab.com.

Director, Enterprise Information Technology

Frontage has an exciting opportunity for a seasoned IT professional to lead our IT group in Exton, PA office. Incumbent will be responsible for overseeing the management of the information technology systems and IT service delivery. systems include software, hardware, printers, mobile devices, data and telephone communication systems, and networks

Major Responsibilities:

- Manages the IT group's strategic planning and governance processes
- Executes strategic plans for acquiring and enabling efficient and cost-effective information processing and communications technologies to achieve business goals.
- Ensures that the operational and information requirements of all functional areas are met effectively and efficiently.
- Ensures IT policies, processes, procedures and controls are implemented and monitors adherence to ensure data recoverability and security, customer privacy and confidentiality, and legal compliance.
- Direct the IT group to design and develop clinical trial applications
- Responsible for managing vendor relationships and maintaining appropriate hardware and software maintenance agreements

Qualifications

- 8 years of IT experience, including 3 years of management experience in a complex enterprise-class network and application environment.
- Experience developing strategies and roadmaps to evolve IT systems and support new business initiatives.
- Extensive experience leading and managing the development and maintenance of enterprise-class technical infrastructures using a standard project management methodology.
- Knowledge of current and evolving computer hardware, software, networking, and security practices.
- Experience in Oracle Database Management or OC desirable.
- Bachelor degree in Computer Science, MS degree desirable.

Interested applicants are invited to send your resume to gzhou@frontagelab.com.

Biostatistician / Senior Biostatistician

Frontage is seeking an enthusiastic Biostatistician / Senior Biostatistician to join our U.S. Biometric operation in Exton, PA office. Incumbent will develop statistical methods sections of protocols and review case report forms (CRFs). Prepare analysis plans and write specifications for analysis files, consistency checks, tables, and figures. Communicate with clients regarding study protocol or statistical analysis issues as they arise. Communicate with study team members or project sponsors regarding study execution as it relates to timelines, data quality, and interpretation of results. Interpret analyses and write statistical sections of study reports.

Major Responsibilities:

- Able to provide statistical consulting independently and prepare statistical sections of protocols
- Perform sample size and power calculation for studies
- Create randomization schedule per study design and relevant specifications
- Review protocols, case report forms (CRFs), data management plans, data specifications and other related study documents
- Develop statistical analysis plans (SAP) independently and prepare analysis data specifications
- Able to develop SAS programs to develop statistical models and complete statistical analyses
- Develop or validate SAS programs to create derived variables and analysis data sets
- Perform senior review of analysis data and TLGs
- Prepare statistical reports
- Review and provide input and interpretation of analysis result to support clinical study report (CSR)

Qualifications:

- Advanced degree (MS or PhD, or equivalent) in Biostatistics or closely related field
- 3-5 years direct advance knowledge of clinical trials design and analysis experience with advanced SAS programming experience in contract research organization (CRO) environment
- Working knowledge of CDISC standards and application of those standards to projects
- Ability to effectively communicate with others on the project team and with project sponsors.
- Ability to work on several projects simultaneously
- Demonstrated knowledge of design of clinical trials and regulatory requirements
- Knowledge of design of clinical trials and regulatory requirements
- Excellent English communication skills (verbal, written & interpersonal)

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Contract Statistical Programmer (Contract –to- hire)

Frontage is seeking several statistical programmers (Contract-to-hire) to join our U.S. Biometric operation in Exton, PA office. The Statistical Programmer(s) will provide advanced technical expertise as part of the Statistical Programming team to develop and maintain programs to meet internal and external clients' needs. Plan and lead the development of project-related solutions to the full scope of statistical programming tasks in term of Tables, Listings and Figures (TLFs).

The initial contract assignment will be 6 months to 12 months.

Responsibility

- Develop statistical programs to support creation and validation of tables, listings and figures for clinical and non-clinical studies
- Build programming specifications for safety and efficacy analysis database based on the Statistical Analysis Plan and report specifications
- Create analysis datasets, tables, listings and figures to support writing of Clinical Study Reports and other regulatory filings
- Document all work with careful attention to traceability and reproducibility
- Validate analysis datasets and tables, listings and figures created by another team member
- Represent the programming group in project team meetings and interact with Biostatisticians, Medical Writers, Clinicians, Data Managers and other programmers
- Review and provide feedback on statistical analysis plans, output specifications and other guideline documents
- Review and provide feedback on CRFs and edit specifications
- Support the writing of final clinical study reports by providing necessary ad-hoc programming
- Contribute to the development the technical infrastructure to expedite operations and improve quality control
- Contribute to the development of CDISC and ADaM data standards

Qualifications:

- Masters in Statistics, Computer Science and related life science discipline plus minimum 2-3 years of experience in the contract research organization (CRO). Bachelor’s degree with minimum 4 years of experience will be considered.
- Proficiency in SAS programming including, but not limited to, Base SAS, SAS/STAT, Macro language
- Excellent verbal and written communication skills is a must
- Skilled in identifying issues related to statistical analysis and basic knowledge in statistics
- Experience with Phase 1 to 3 clinical trials, ISS/ISE and regulatory submission is highly desirable
- Experience with CDISC SDTM and/or ADaM is highly desirable
- Ability to work on several projects simultaneously

Interested applicants are invited to send your resume to gzhou@frontagelab.com.

Study Manager, Clinical Data Management (FTE or Contract –to- hire)

Frontage is seeking several statistical programmers (Contract-to-hire) to join our U.S. Biometric operation in Exton, PA office. Incumbent manages the design, development, modification, and evaluation of systems for collecting and organizing clinical study data to identify, analyze, and report data and trends. Including but not limited to the development and design of case report forms; development of clinical data management plans; identifies and resolves data anomalies; over sees data validation efforts; interacts with project management staff to assure compliance with project timelines and deliverables.

The initial contract assignment will be 6 months to 12 months.

Major Responsibilities:

- Leads study setup activities including CRF, data management plan and database design
- Performs routine data management and analysis activities
- Identifies, investigates, and resolves data anomalies and discrepancies
- Reviews data output and distributes data summaries
- Oversees the design, validation efforts and documentation of clinical data system and statistical analysis methods.
- Ensures data management methods, equipment, and practices are in compliance with FDA regulations, GCP guidelines, and internal SOPs
- Interfaces with clients to assess data management needs and deliverables
- Basic SAS programming for data mapping desirable

Qualifications:

- Requires excellent written and oral communication skills
- Requires a BS or MS in a data related fields and/or health care field (e.g., nursing, pharmacy, physician's assistant)
- Minimum of 5 years' work experience in the clinical research industry with 3 years' experience in clinical data management for a contract research organization (CRO)
- Experienced with operations of clinical data management systems and Oracle Clinical Database
- Knowledgeable in all aspects of the Federal (FDA) regulations and requirements governing the conduct of clinical trials including, but not limited to, GCP and ICH requirements
- Familiarity with SAS programming or SQL query preferred
- Strong clinical data knowledge and medical terminology
- Strong work knowledge in Paper-based systems and Electronic Data Capturing Systems

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