

Job Opening #1

DIRECTOR, QUALITY ASSURANCE-CHINA OPERATIONS for Frontage Laboratories

LOCATION: Beijing or Shanghai CHINA

TO APPLY: SEND RESUME TO: GVERDI-FRANCESCO@FRONTAGELAB.COM & REFERENCE JOB TITLE IN SUBJECT LINE

DUTIES:

Exciting opportunity for an experienced Director, Quality Assurance in our Beijing or Shanghai China location. The ideal candidate will have prior experience working as a Quality Assurance professional in the pharmaceutical, biotech, medical device or other life science industries with a US or EU-based pharmaceutical company.

QUALIFICATIONS:

- BS/MS in scientific discipline, regulatory affairs, or quality assurance
- Minimum of ten (10) years relevant experience in pharmaceutical industry
- Strong knowledge in pharmaceutical regulations and guidance for GMP, GLP, GCP

RESPONSIBILITIES:

- Manage and implement the overall quality program for Frontage Laboratories (China) in coordination with the Quality leadership team in the USA
- Responsible for mentoring and monitoring the quality leaders in charge of CMC/CTM Manufacturing; BIO/GLP and Clinical Services in China
- Prepare, review and/or approve: SOPs, protocols, reports, SOPs related to Quality as needed
- Facilitate communication and interact with management and clients to resolve compliance issues
- Performs corporate internal oversight audits
- Provides regulatory inspection support to local QA as needed
- Provides client/sponsor audit support to local QA as needed

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NO RECRUITERS OR AGENCIES

Job Opening #2

TITLE: DIRECTOR, BIOLOGICS SERVICES-(IMMUNOCHEMISTRY)

LOCATION: MALVERN, PA

TO APPLY: SEND RESUME TO: GVERDI-FRANCESCO@FRONTAGELAB.COM & REFERENCE JOB TITLE IN SUBJECT LINE

DUTIES:

The ideal candidate will have a minimum of ten (10) years of pharmaceutical industry experience involved in regulated drug discovery and development. Experience developing and validating

Immunogenicity (anti-drug antibody) assays. The Director will have hands on experience and knowledge of Ligand binding assays. (e.g. ELISA, MSD, Biacore etc). Familiarity with FDA Bioanalytical method validation guidance, and industry guidance on Immunogenicity method validation. The candidate must have experience working in a matrix team, especially across disciplines and departmental lines is helpful. Experience with MSD or Electrochemiluminescent (ECL) Immunoassay preferred. Responsibilities:

QUALIFICATIONS:

- BS/MS or PhD in Immunology or equivalent, plus 10 years related experience.
- CRO experience preferred.
- Training in leadership skills and management skills.
- Training in GLP regulations and ICH guidelines.
- Experience working in a GLP environment
- Strategic planning or development experience

RESPONSIBILITIES:

- Scientific and regulatory leadership within the Frontage Bioanalytical services organization. Responsible for large-molecule bioanalytical activities.
- Consult with clients on drug discovery or development needs and establish appropriate immunochemistry assays or programs.
- Client interaction and influencing the external scientific and regulatory environment are significant components of this role.
 - Develop and execute a strategic plan which identifies the areas in which the department will concentrate its scientific efforts, capital, and staff to meet growth objectives.
 - Initiate, plan and implement staff development programs.
 - Directs a staff responsible for the scientific conduct of immunochemistry projects methods development and validation.
- Directly interacts with scientific and operational personnel.
- Serve as internal and external technical expert.
 - Directly interacts with external clients and industry professionals.
- Develop and execute the operational plan to achieve scientific, capital and staff growth objectives.

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Job Opening #3

TITLE: DIRECTOR OF CLINICAL RESEARCH CENTER

LOCATION: HACKENSACK, NJ

TO APPLY: SEND RESUME TO: GVERDI-FRANCESCO@FRONTAGELAB.COM & REFERENCE JOB TITLE IN SUBJECT LINE

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DUTIES:The Director of Clinical Research Center will provide leadership for the overall financial, scientific, and administrative activities with respect to planning, implementation, and quality of all

projects performed at the Frontage Clinical Research Center. He/She will be responsible for overseeing day-to-day operations in compliance with GCP guidelines, applicable regulations and approved protocols. Lead/manage physicians, study nurses and coordinators, lab technicians, and other supporting staff members. Maintain and develop the relationships with existing and new clients.

QUALIFICATIONS:

- 10+ years of clinical research experience with a MS or MA degree from an accredited college or university (5+ years with an MD, PhD, or PharmD)
- 5+ years of managerial exp in hospital, industrial Phase I clinical research or academic centers.
- Familiarity with all elements of Good Clinical Practice in the conduct of human subjects research.
- Excellent oral and written communication skills in clinical, scientific and research fields.
- Evidence of program development in academic, hospital or industrial research.
- Proficient in data analysis, protocol preparation, presentation to local, regional and/or national audiences.

RESPONSIBILITIES:

- Oversee and manages Clinical Research Center operations, including the implementation of Phase I studies in healthy volunteers and outpatient Phase II-IV clinical studies in selected patient populations.
- Manage implementation of Phase I-IV clinical studies in compliance with company SOPs, and applicable regulations and GCP guidelines.
- Business development activities, including overall recruitment strategies, initiating new client contacts, maintaining existing client relations.
- Financial analysis and study budget preparation for clinical studies performed at Frontage Clinical Research Center.
- Establish strategic relationships with physician specialists (cardiologists, endocrinologists, urologists, ophthalmologists, fertility/reproductive medicine clinic, radiologists) and scientists in the surrounding medical and scientific community and adjacent medical centers.
- Establish and maintain relationships with Institutional Review Boards
- Provide input into study protocol feasibility assessments and study protocol design.
- Project manager responsibilities including serving as a primary sponsor liaison, tracking the overall project status, supervising research subject recruitment efforts, scheduling of full-time and per diem staff, establishing and maintaining key vendor relationships (clinical laboratory, medical supplies).
- Develop a high level of familiarity and knowledge of the study protocol and flow chart of study procedures. Develop a strategy for implementing study procedures in compliance with the study protocol.
- Senior clinical study coordinator activities as required for individual clinical studies.
- Acts independently to determine methods and procedures on new assignments and may supervise the activities of other Clinical Research Center personnel (*e.g.*, Laboratory and Medical Technicians/ Assistants, Administrative Assistants, and Recruiters).
- Experienced Clinical Research Coordinators may train other Clinical Research Coordinators and support personnel in applicable regulations and GCP guidelines as they pertain to conducting clinical studies.

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