Position: CLINICAL RESEARCH COORDINATOR/MANAGER

Position Summary

The position holds responsibility for coordinating and overseeing the clinical development plan as outlined by various in vitro diagnostic product development projects within the Company and for defining and developing objectives, strategy, and studies for an anticipated growing Clinical Trials Department. The position will initially oversee establishment of Good Clinical Practices (GCP) consistent with FDA/ICH Guidelines, and all aspects of planning, development, execution, oversight and reporting of clinical studies in support of product regulatory submissions, and support of regulatory submissions development. Studies will include both clinical specimen collections for exploratory and preclinical R&D studies, interaction with contract Clinical Research Organizations (CRO), and where justified, development of directly managed clinical trials by the Company. This is a management track position which will have the ability to guide and direct the scope and strategy of Clinical Trials capabilities in the Company.

FLSA Status: Exempt

Reports to: Chief Science Officer

Duties and Responsibilities

- Act as primary Company interface with outside parties (CROs, physicians and clinical site personnel, institutional review boards [IRBs], regulators) on Company Clinical Trials matters.
- Develop internal record keeping system(s) and procedures consistent with GCPs, including maintaining and auditing data and providing status and activity reports as required.
- Coordination of clinical development plan as outlined by diagnostic product development projects or the Company, defining objectives, strategy and studies.
- Provide support for planning including detailed effort estimates, scheduling, and critical path analysis.
- Monitor clinical activities to identify issues, variances, and conflicts and analyze and recommend solutions.
- Identify clinical project staffing requirements and tracking investigational product supply to outside sites as well as providing ongoing, objective updates on progress and problems with projects.
- Collaborating with various departments on the design, documentation, testing and implementation of clinical data studies.
- Develop systems for organizing data to analyze, identify and report trends.
- Evaluates and analyzes clinical data and coordinates activities of associates or CROs to ensure compliance with protocol and overall clinical objectives.
- Overseeing clinical data entry and validation to ensure legibility, completeness, and consistency of data.
- Oversees management of Company clinical specimen bank.
- Must be able to operate in a Bio Safety Level 2 Laboratory with blood-borne pathogens with training provided.

Minimum Requirements and Qualifications

- Bachelor's degree in a Bioscience, Health Science, or related field, a registered nurse degree, or equivalent, with a minimum of 2-5 years clinical experience in medical research, nursing or the pharmaceutical or diagnostics industry.
- Must have prior relevant experience in managing, overseeing or executing in a substantive way one or more clinical trials.
- Must be familiar with the scientific/investigative process.
- Good written and oral communication skills; good ability to communicate easily not only with other company employees, but outside parties including IRBs, physicians and/or their staff, CROs and clinical site personnel.

- Familiarity with MS Word, Excel required, and MS Outlook preferred.
- Must be able to occasionally travel domestically and internationally to field sites to supervise and coordinate clinical studies. Required travel time not expected to exceed 10% of work days annually.
- Excellent attention to detail, time management and organization skills.
- Self-starter, able to take initiative requiring only general strategy and supervisory oversight.
- Performs well under pressure and can work to deadlines.

- Prior project team experience and familiarity with FDA/ISO Design Controls and FDA/WHO PQ in vitro diagnostic regulatory requirements is highly desirable.
- Phlebotomy experience considered a plus.
- Familiarity with Outlook and database management desirable.

Position Title and Compensation Package dependent on experience. Benefits include paid medical, dental and vision insurance and paid time off.

APPLICATION INSTRUCTIONS

Please read carefully. We consider attention to detail an important qualification for new hires. Improperly prepared or submitted applications may be delayed in routing to the appropriate hiring manager or may not be considered.

Only candidates who apply with a resume and cover letter by email or U.S. mail will be considered. First and Last Name, Mailing Address and Contact Information (email address, phone number or preferably both) must be provided. Be sure your cover letter clearly states the position(s) for which you are applying and any preferences about how to contact you.

Application by Email:

This method is preferred and will receive the fastest consideration. Submit your resume and cover letter as an attachment in either RTF, Word, or PDF format to jobs@sediabio.com. **No other formats including links to other internet addresses will be accepted and emails with such links will be deleted without opening.**

In the Subject Line of your email, enter: "*Your last name, your first name, middle initial (middle initial optional), and Job Title (that you are applying for)".* For example, "**Smith, Mary R, Senior R&D Scientist**". If you are applying for multiple positions, please submit separate emails for each position. If you do not use this format, your application may be delayed in getting to the hiring manager.

Application by U.S. Mail:

Submit your resume and cover letter to the address below. On the mailing address outside, send to the attention of HR indicating the position you are applying for. You may list multiple positions in the attention line. Only one cover letter/resume needs to be sent if you are applying for multiple positions.

Sedia Biosciences Corp.
Attention: HR (*List positions you are applying for, separated by commas, here*).
4900 NE 122nd Ave.
Portland OR 97230

ABOUT SEDIA BIOSCIENCES

Sedia is a privately held medical device and diagnostics company founded in 2009 and based in Portland Oregon. Sedia is committed to the development of novel epidemiological and diagnostic assays and clinical specimen collection products intended to expand access to healthcare worldwide. For additional information, see our website at www.sediabio.com.