CYCLACEL

Sr. Manager/Director, Clinical Operations

Location: Berkeley Heights, New Jersey, US

DUTIES & RESPONSIBILITIES

Reporting to the President and CEO, in this hands-on role you will independently manage clinical operations relating to our investigational drugs: including execution of clinical studies, have responsibility for project planning; budget and resource management, CRA and CRO management, ensuring that operational aspects of the clinical trials are performed effectively. Specific responsibilities include:

- Contributing to effective planning of optimized trials, including clinical operations aspects, study protocols, CRF, operations manual, investigator brochures, site training materials and study-related contracts/budgets.
- Managing vendors, including CRO and data management selection and contract negotiations, cultivating support from key opinion leaders.
- Establishing and maintaining productive relationships with clinical sites.
- Managing clinical operations, including organization and supervision of CRAs; recruiting trial sites, establishing timelines, supervise budget administration with help of finance team to ensure on-time and on-budget drug development.
- Designing and overseeing conduct and reporting of clinical trials, including overseeing receipt, review, revision and filing of study documentation in Trial Master File, data cleaning and database locking, reviewing data listings to ensure studies are conducted according to GCP, audit standards, country specific regulations and departmental SOPs.
- Assisting in writing the clinical sections of regulatory documents.
- Providing clinical operations expertise to staff as needed and reviewing operational practices and systems for efficiencies and cost controls.
- Playing a central role in building and maintaining relationships between clinical development and regulatory, Q&A and finance.
- The role will involve extensive US and limited international travel.

EDUCATION

- RN or BS or MS or MPH in clinical trial sciences or pharmacology or related field.

KEY SKILLS & EXPERIENCE

- At least seven years of US biopharma industry experience; including a minimum of three years as a project manager for Phase 1-3 trials in hemato-oncology at a biopharma company; early-stage biotech a plus

- Demonstrable experience in execution of clinical trials and building clinical operations functions using external resources; plus extensive experience in developing relationships with clinical trial sites

- Demonstrable expertise in drug development, clinical design and investigator relations

- Well-developed communication and relationship skills to operate collaboratively with a small core of key individuals in a virtual organization; able to work independently, and also interact at a higher level as required in a biotech environment

- Demonstrable ability to write and edit technical documents, such as protocols, amendments, informed consent and other trial documents

- Ability to bring a high attention to detail and be able to multi-task while managing a variety of complex projects

- Excellent software skills (MS Office Outlook, Project, Word, Excel, PowerPoint, and EDC software; familiarity with Rave a plus)

- Strong working knowledge of FDA, ICH, GCP guidelines, CFR, EMA, and HIPAA regulations; and will be current with industry regulations

- Potential to grow the clinical operations team as the number and complexity of clinical trials run by the company increase

- Flexibility in multicultural settings and willingness to travel.

This job description describes the general duties of the position and provides some illustrative examples. Other duties may be assigned by management as business circumstances require.

To apply for the above position, please send your CV with an accompanying letter either via email to recruitment@cyclacel.com; or by post to Human Resources, Cyclacel Pharmaceuticals Inc., 200 Connell Drive, Suite 1500, Berkeley Heights, NJ 07922.

Closing date for applications is **March 5, 2018**.

We look forward to hearing from you.

Cyclacel Pharmaceuticals, Inc. is an Equal Opportunities Employer.

This job description describes the general duties of the position and provides some illustrative examples. Other duties may be assigned by management as business circumstances require.