Clinical Research Manager

Job Reference: CRM
Posted: January 2024

Location: Carlsbad, CA
Weekly Hours: 40

The Role
DNA Electronics (DNAe) is a dynamic company integrating cutting edge sequencing technologies with novel biochemical techniques to create a revolutionary sample-to-answer sequencing platform. We are seeking a strong individual to contribute to the DNAe team. The qualified applicant will be responsible for all clinical studies sponsored by DNAe for sample acquisition for research and development purposes and pivotal clinical studies.

Responsibilities:

- Maintenance of Sample Acquisition Studies
  - Running all aspects of the studies
  - Logistics
  - Supplies coordination
  - Specimen inventory management
  - Collaboration development
  - Internal clinical testing coordination
  - Clinical data management system (REDCap EDC platform preferred)

- Liaison for the Contract Research Organization (CRO) in support of the Pivotal Clinical Study for the LiDia-SEQ Sequencing System and BSI/AMR Assay
- Internal support for preparing and supplying Clinical Study materials (reagents, supplies, documentation etc.) for external research and clinical studies
- Coordinates clinical operations including design, initiation, coordination of clinical trials to support regulatory submissions, as well as marketing studies and post-market clinical trials.
- Provides ongoing CRO oversight.
- Coordinates the preparation of state-of-the-art study documentation, including protocols, statistical data analysis plans, monitoring plans, informed consent forms, case report forms, investigator agreements and financial agreements, as required.
- Ensures compliance with all applicable regulatory standards related to clinical trials and interactions with physicians. Continues to increase knowledge of medical device development process, ICH-GCP, FDA regulations and any other applicable local/international regulatory requirements.
- Assists in updating company Standard Operating Procedures (SOPs) to support adherence to company policies and procedures concerning Clinical Affairs.
- Responsible for the financial management of the clinical trial program including budget planning, and investigator payments as applicable.
- Plans and manages study site activities and provides ongoing updates of site status to management.

- Supports Regulatory Affairs with clinical sections of regulatory submissions, and study related communication with regulatory agencies. Collect, review, and track regulatory documents when required.
- Accurately completes administrative activities in a timely manner.
- Interfaces with other departments (R&D, Product Management, Legal, Regulatory and/or Quality) to represent the clinical department. Works closely to establish collaborative relationship with clinical trial investigators.
- Other duties as assigned

Person Specification

We are looking for people with a passion for their work - people who strive for exceptional results, but who can deliver pragmatic solutions on time. DNA Electronics' scientists and engineers enjoy and thrive on working in an interdisciplinary team but can also work independently and use their own initiative.

Qualifications & Experience:

- Bachelor's Degree in Life Sciences or like discipline and 5+ years' experience in similar role, or equivalent working experience is required. Preferably an MS degree.
- Clinical Trial Certification desirable. Project management certification or relevant experience is a plus.
- Strong interpersonal, verbal and written communication skills.
- Detail oriented, excellent organizational and management skills.
- Thorough knowledge of ICH guidelines and Good Clinical Practices (GCP) governing the conduct of clinical trials.
- Knowledge of electronic data managements systems. Experience in the use of electronic data management systems is a plus.
- Must be computer literate with working knowledge of Microsoft Office.
- Three or more years of experience in clinical research required, preferably in the IVD diagnostic or medical device industry.
- Proven track record of conducting successful clinical research studies for an IVD or medical device company or CRO.
- Experience with design and development of clinical investigational plans to support regulatory submissions.
- Experience in collaborations with hospitals and physicians.
- Proven ability as an effective people manager with leadership abilities Education
- Strong organizational and problem-solving skills in a fast-moving pressured environment where changing priorities are the norm.

Location

DNAe Carlsbad, California

Apply

If you believe you meet the above criteria and would relish playing a key role in developing a revolutionary technology, we would be delighted to hear from you.

We offer a competitive compensation package to successful candidates.

Please email your CV and cover letter to: HR-US@dnae.com quoting

Your name and the job title in the subject line.

For more information about DNAe, please visit our website www.dnae.com

DNAe is committed to offering staff a competitive remuneration package, alongside compelling benefits. As the primary part of the process, we conduct a rigorous market data review where each role is individually benchmarked using a vast amount of recent data. The estimated base salary range for the Clinical Research Manager role based in Carlsbad, California is: $116,415 to $129,350. Compensation decisions are dependent on several factors including, but not limited to, an individual's qualifications, location where the role is to be performed, internal equity, and alignment with market data. Should the level or location of the role change during the hiring process, the applicable salary range may be updated accordingly.

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