**Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.**

**Clinical Research Associate, Senior (Long-Term Temporary Opportunity)**
***(Job: 09-17BA)***

**About Ambrx:**
Ambrx, Inc. is a biopharmaceutical company with a mission to deliver breakthrough protein therapeutics. Ambrx is based on a fundamental advance in protein biosynthesis that enables the company to genetically engineer proteins with new amino acid building blocks beyond the common twenty, enabling the biosynthesis of proteins with new physical, chemical and pharmacological properties. At Ambrx, we are dedicated to assembling and developing an exceptional team and a breakthrough technology to create the next generation of protein-based medicines.

**Responsibilities:**
This is a long-term temporary Clinical Research Associate, Senior position. The ideal candidate will lead activities associated with the evaluation, initiation and management of clinical studies to ensure compliance with SOPs, FDA regulations and ICH/GCP guidelines. Leads clinical study team meetings, including oversight of CRO and vendors. The Clinical Research Associate, Senior is responsible for:

1. The preparation and finalization of project and study-related documents including informed consent forms, clinical trial plans, synopses, protocols and amendments, IND Annual Updates and clinical summaries, as required.
2. Identifies and responds to site, vendor and study related issues and recommending corrective actions and/or escalating to supervisor.
3. Coordinates and manages Investigational Product including overall accountability and reconciliation.
4. Monitors and tracks clinical trial progress and providing status update reports.
5. Manages clinical trial vendors (e.g., IVRS, central labs, IRB, and central ECG).
6. Partners with other research and development groups to achieve deliverables.
7. Participates in the development of Clinical SOPs/workflows and providing appropriate feedback to interdepartmental SOPs.
8. Performs other duties as assigned.

**Qualifications:**
Ideal candidates must have:

- Knowledge of ICH/GCP guidelines and FDA regulations
- Demonstrated expertise in relevant clinical operations activities
- Ability to problem solve and delegate appropriate tasks to subordinates
- Strong leadership skills, self-motivated, adaptable to a dynamic environment
- Ability to exercise independent judgment within generally defined practices and policies that lead to methods or processes for obtaining results
- Strong interpersonal skills and communication skills (both written and oral)
- Ability to collaborate effectively with the study team, cross-functional team members, and external partners
- Ability to “roll-up your sleeves” and contribute results to a Research and Development effort.
- Good organization and planning skills
- Proficiency in MS Word, Excel and PowerPoint
- Must be willing to ravel up to 25% of the time

<u>Education/ Training:</u>

- BA/BS/MS
- 4+ years of relevant clinical experience in a CRO or pharmaceutical industry
- At least 3 years of CRA experience and 2 years of study management experience preferred
- Experience in oncology preferred
- Experience in global trials preferred

To be considered as an applicant, please submit your resume/CV referencing the specific position of interest and position code to careers@ambrx.com. Applicants whose qualifications and experience most closely match the requirements of the position will be reviewed. Candidates will only be contacted for evaluative discussions. Ambrx offers competitive compensation & benefits.