Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.

Clinical Study Manager/Associate Director

(**Job Code: 04 – 19BA**)

Ambrx is a clinical-stage biopharmaceutical company with a mission to deliver breakthrough protein therapeutics through our proprietary technology. Unlike conventional conjugation technologies that creates a mixture of suboptimal molecules, Ambrx technology incorporates non-natural amino acids beyond the common twenty into the protein biosynthesis, enabling site specific conjugation of payloads, pharmacokinetic extenders with proteins to create novel homogenous molecular species that is optimized for safety, efficacy and biophysical properties.

Ambrx is seeking a highly motivated Clinical Study Manager/Associate Director to be a key member of the clinical team in a fast-paced and dynamic environment. This position will be responsible for planning, initiating and executing clinical studies with a focus on operational excellence and regulatory compliance.

Major Responsibilities:

- Oversee all operational aspects of assigned clinical trials, drive excellence in clinical operations to ensure compliance with regulatory and GCP requirements to attain high quality and efficient clinical conduct and achieve established goals within timelines and budget
- Develop and execute study materials, such as, protocol, ICF, CRFs, study monitoring plans, pharmacy manuals, site initiation presentation deck, site management plans, data management plan, and protocol deviation management plan, etc.
- Play a key role in clinical CROs/vendors selection, budget negotiation and contract approval for clinical programs at different development stages according to regulatory guidance and internal SOPs. Work with QA, Legal and Finance to ensure assumptions, scope, vendor responsibilities, and payment terms are clearly defined.
- Manage CRO and central lab activities, monitor study conduct closely to ensure GCP compliance and milestone deliverables. Review CRA monitoring reports, proactively identify and timely address any potential concerns and issues.
- Prepare regular status updates to senior executives. Plan and conduct internal and external meetings such as cross function team meetings, corporate updates, SMC meetings, investigator meetings and KOL meetings, etc.

Job Qualifications:

- BS or MS or Ph.D. in a biological science related field.
- 10+ years of relevant experience in the clinical trial monitoring and management
- Excellent English written and verbal communication skills
- Strong interpersonal skills with an ability to confidently interact with key internal and external stake holders including department heads, senior management, physicians, administrators, and consultants
- Successful track record in managing phase 1-3 clinical studies
- Proven organizational and collaborative skills essential
- Prior experience in conducting MRCT is a plus
- Willing to travel up to 15% for SIV, co-monitoring, and coordinating investigator meetings
- Must be self-motivated, detail-oriented, results driven and able to work effectively in a fast-paced environment with minimal supervision

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 experiences most closely match the requirements will be reviewed. Candidates will only be contacted for evaluative discussions. Ambrx offers competitive compensations & benefits. EOE.