Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.

Clinical Study Manager/Senior Clinical Study Manager

(**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/Senior Clinical Study Manager 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
- Work with internal stakeholders (clinical, legal, QA, finance) in line with company SOPs to select most suitable clinical CROs and vendors for clinical programs at different development stages, ensure assumptions, scope, vendor responsibilities, and payment terms are clearly defined through final contract approval
- Apply expertise in day to day clinical operations activities, collaborate with internal and external cross functional team members to develop study documents and manuals, including, protocol, ICF, CRFs, study monitoring plans, pharmacy manuals, site initiation presentation deck, site management plans, data management plan, and protocol deviation management plan, etc
- Coordinate site selection and Principal Investigator identification activities, including identification of KOLs
- Closely monitor and track study activities, ensuring timely data entry, query resolution, and prompt resolution of sites issues. Review CRA monitoring reports, proactively identifying and addressing study conduct issues

- Track PK sample collection, shipment, and analysis to ensure protocol adherence timely reporting of PK data
- Prepare status reports for internal and external team meetings, providing regular updates to senior executives

Job Qualifications:

- BS or MS in a biological science related field or equivalent experience with 10+ years of relevant experience in the clinical trial management
- Working knowledge of US FDA GCP requirements, and ICH guideline. Prior experience in conducting MRCT is a plus
- 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
- Willing to travel up to 15% for SIV, co-monitoring, and coordinating investigator meetings
- Excellent English written and verbal communication skills
- Must be self-motivated, detail-oriented, 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.