Opportunity with San Diego Biopharmaceuticals – Ambrx, Inc.

Clinical Operations Director

(31-21BA)

About Ambrx:

Ambrx Inc., is a clinical-stage biopharmaceutical company focused on developing Precision Biologics using an expanded genetic code. Ambrx technology uses an expanded genetic code to incorporate synthetic amino acids into protein, all completed within a living cell. These synthetic amino acids enable the creation of Precision Biologics, an exciting new class of therapeutics with broad application and potential. This includes next-generation antibody drug conjugates (ADCs), bispecifics, and targeted immuno-oncology therapies for cancer as well as smart cytokines to modulate the immune system, and long-acting therapeutic peptides for metabolic and cardiovascular disease.

Job Description:

We are seeking a highly motivated and experienced Clinical Operations Director to join our fast paced and growing Clinical team. This position provides expertise and leadership in Clinical Operations and is responsible for overseeing multiple simultaneous oncology clinical studies of all phases (phases 1-3) including project planning, budgeting, resource management. The candidate should be accountable for the implementation, management, and execution of the national and/or global oncology clinical studies which includes budget, contract, enrollment, site activities, resource management and deliverables.

Job Requirements and Qualifications:

- BA/BS in Science, RN, Pharm D, Master's degree preferred.
- 15 years of experience in Clinical Operations with strong global oncology trial management experience.
- Demonstrated prior success in the managing the conduct of phase 1-3 global oncology clinical studies.
- Excellent oral/written communication and organizational skills
- Strong interpersonal and project management skills.
- Proven ability to lead multi-functional teams. Must be proactive and self-disciplined.
- Strong working knowledge and applicable understanding of CFR and ICH guidelines.
- The ability to distinguish matters that warrant supervisor knowledge or input from those matters that do not.
- Develop operational plans for multiple clinical studies (e.g. study timeline projection, drug and budget forecast, safety plan, monitoring plan, study management plan, issue escalation and resolution plan).
- Prepare and negotiate budgets and contracts with each study center.
- Initiate and track payments made to study sites and vendors.
- Organize and present at clinical sites and external project meetings as required.
- Responsible for the overseeing the performance of clinical CROs, Contract Laboratories, other vendors.
- Supervise direct reports including CTAs, CRAs, and CTM, etc.
- Must be able to review clinical study tables and listings to ensure clinical data integrity.
- Regulatory inspection support experience preferred.
- Willing/able to travel 20% - 30%, valid, current passport

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.