Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.

Assistant Project Manager, Clinical Stage Project Development

(Job: 02-18BA)

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. Ambrx is seeking a highly motivated project manager to be a key member of a fast-paced and dynamic organization.

This position will be responsible for assisting the Director with managing clinical trial supply and clinical sample logistic projects, coordinating cross functional activities and facilitating team meetings. This position requires the ability to handle complex projects in the clinical development stages while managing priorities and maintaining a critical path toward regulatory compliance. Other activities include project documentation, tracking and communicating project performance.

Major Responsibilities:

- Coordinate cross functional meetings, plan meeting agendas, scheduling and recording minutes, facilitating meeting discussions, following up on action items to ensure deliverables and timelines, maintain quality and compliance.
- Monitor CTM usage, inventory and shelf-life. Work closely with relevant stakeholders to develop clinical trial materials re-supply strategy and timeline.
- Design CTM labels and obtain approval by all applicable functions for use prior to the start of the study, or prior to the re-supply of new batches.
- Document any changes according to applicable SOPs and regulatory requirements.
- Oversee importation/exportation of finished pharmaceutical products, APIs and other clinical trial materials.
- Manage cold chain, temperature excursion reporting and disposition, and drug accountability. Collect and file appropriate documents.
- Oversee clinical central lab activities on clinical sample logistics including kits supply, tracking clinical sample collection, importation/exportation, testing, and reconciliation.
- Review CRO activities and invoices, track expenses in comparison to approved budget and proactively works with team to stay within budget, assess and justify any scope changes.

- Assist the development, review, and distribution of clinical study related documents, and the preparation for SMC meetings and regulatory submissions.
- Maintain project information, communicate and drive functions to meet the timelines, deliverables, and goals with a focus on quality, cost and compliance.
- Contribute to the financial and resource planning systems and processes to coordinate department-level budgets.

Qualifications/Requirements:

- BS, or MS in a biological science field, or equivalent experience, with 5+ to 10 years of relevant experience in the biopharmaceutical industry.
- Prior experience managing global clinical trial supply, including country specific importation/exportation compliance, temperature excursion reporting and disposition, monitoring CTM usage and inventory, working closely with CMC, regulatory and QA representatives to develop re-supply strategy and timeline.
- Experience in managing clinical PK sample logistics is a plus.
- Prior experience managing cross-functional activities, regulatory reporting and submission of clinical stage projects.
- Ability to manage complex projects and outsourcing vendors in a biotech pharmaceutical environment.
- Experience in managing CRO relationships with proven written / verbal communication and negotiating skills.
- Ability to foster a culture of teamwork.
- Excellent organization skills, self-starter with attention to details.
- Strong time management, analytical and organizational skills