Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.

Clinical Supply Logistics Manager

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 clinical supply manager to be a key member of a fast-paced and dynamic organization.

This position will be responsible for assisting the Clinical Operations 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:

- Responsible for clinical trial materials (CTM) supply planning, labeling and packaging, importation and exportation permits for international shipments to depots and clinical sites, inventory monitoring and drug reconciliation management through IWRS systems, cold chain integrity and temperature excursions reporting and materials disposition.
- Analyze demands for clinical trial materials by working closely with clinical team and studying protocols. Develop manufacturing forecast and corresponding timelines for manufacturing drug substances, intermediates and drug products, etc.
- Coordinate cross functional CMC manufacturing activities to ensure timely and cost effective CTM resupply. Facilitate the development of regulatory strategies for lot release, drug product shelf life and CMC changes to ensure regulatory compliance of CTM resupply.
- Support clinical trials in various areas including logistics of clinical PK sample inventory, shipment and testing, timely data analysis and documentation, etc.
- Provide budget negotiations, vendor selection, and relationship management. Manage work order/budget changes and invoicing, and oversee deliverables and issue escalation.

Qualifications/Requirements:

- BS, or MS in a biological science field, or equivalent experience, with 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.
- Ability to manage complex projects and outsourcing vendors in a biotech pharmaceutical environment.
- Excellent organization skills, dedication and accountable, strong time management, self-starter with attention to details.
- Prior experience managing cross-functional activities, regulatory reporting and submission of clinical stage projects.
- Experience in managing clinical PK sample logistics is a plus.