Position:

Senior Manager, CMC Project Management

About the Company:

Dren Bio (the "Company") is a privately held, pre-clinical stage biopharmaceutical company focused on developing therapeutic antibodies for the treatment of cancer, autoimmune and other serious diseases. The Company's management team and scientific advisors have profound expertise covering the discovery and development of engineered antibodies designed to selectively target and deplete pathological cells. Dren Bio's pipeline is currently comprised of two distinct programs. The first program surrounds DR-01, the Company's lead product candidate, which induces antibody-mediated killing of a cell type that is responsible for a multitude of hematologic malignancies and plays a key role in various autoimmune diseases. The Company's second program is a proprietary antibody-based technology platform, its Targeted Myeloid Engager, which utilizes a novel mechanism of action to selectively engage myeloid cells for the targeted depletion of diseased cells and disease-inducing agents, as well as to induce immunostimulation.

Function:

CMC Project Management

Level:

Senior Manager

Location:

Redwood City, CA

Reporting Manager:

Executive Vice President, Process Sciences and Manufacturing Operations

About the Opportunity:

Dren Bio is seeking a highly motivated individual to support CMC project management for the Company's pipeline programs. The successful candidate will manage internal and outsourced CMC activities for specified projects at all development stages and be involved in interactions with contract development and manufacturing organizations (CDMOs) and contract research organizations (CROs). This position offers excellent potential for contribution and visibility at an early-stage company and opportunities for career development.

Role and Responsibilities:

- Lead CMC team organizational meetings and ensure clear agendas are set, actions and decisions are documented and communicated to meet CMC project timelines.
- Serve as the primary point of contact for CMC project management activities internally and externally with CDMOs and CROs. This includes activities such as cell line development, drug substance/drug product manufacturing, labeling/packaging, and distribution for clinical studies. Proactively track and manage activities at CDMOs and CROs, and facilitate resolution of issues to keep project activities on track.
- Maintain frequent communication with the cross-functional CMC project team members and key internal stakeholders so that all parties are aware of current project status, issues, contingencies, and milestones.
- Ensure that management and teams are kept apprised of progress against plans, and changes. Regularly communicate project status including expectations, opportunities and risks via written communication as well as presentations, discussions and informal interactions.
- Ensure project plans and objectives are clearly established and communicated. Create timelines and utilize planning tools such as decision support models and Gantt charts. Work with other project managers to integrate CMC timelines and deliverables with the overall project plans.
- Proactively identify CMC critical path activities, risks and impediments to successful development and work within the team to identify solutions to mitigate these risks.
- Build strong working relationships across departments and with key stakeholders to ensure transparency and to facilitate communication.
- Coordinate preparation and review of CMC regulatory filings.
- Create purchase orders, invoice tracking/payments, accruals and reforecasting on a quarterly basis.
- Some US and international travel required.

Education, Experience and Qualification Requirements:

- BA/BS in or higher degree in life sciences, chemistry, engineering, or equivalent related discipline with 8-10 years of experience in the biopharmaceutical industry including CMC project management experience. Prior technical experience in process development/CMC area is required. PMP certification preferred.

Core Competencies, Knowledge and Skill Requirements:

- Demonstrated experience with CMC operational efforts on biologic products.
- Technical experience in CMC development of a biologic product required.
- Proven ability to manage competing priorities, budgets, and timelines in a fast-paced, rapid-growth environment.
- Highly skilled at working collaboratively with cross-functional teams and contractors to drive results and meet company objectives.
- Ability to distill, organize, and effectively communicate (verbal and written) key messages from complex discussions.
- Self-directed and proactive with ability to function independently in certain situations, exercise good judgment and respond quickly and effectively to changing environments.
- Ability to deal with uncertainty, unanticipated challenges in a constructive manner and generate options for moving forward.
- Demonstrated ability to utilize project management tools successfully; strong computer skills and experience with software such as MS Project, Excel, SharePoint.
- Adequate knowledge of cGMP, US and EU regulations.
- Experience working with CMC teams and managing relationships with CMOs/CROs is preferred.
- In-depth knowledge of some aspects of the biopharmaceutical industry, drug development (ex. cell line development, process/analytical development, manufacturing, drug substance/drug product, formulation and regulatory approval process) is preferred.
- Early-stage clinical development and IND experience is preferred.

Salaries, Benefits and Other Employee Perks:

Dren Bio strongly believes in investing in, and rewarding, its employees. This philosophy is embodied in the Company's total rewards program, which includes competitive cash compensation, equity incentive awards, and employer sponsored benefit offerings. Exact cash and equity compensation shall be commensurate with candidate's experience and qualifications.

Employment Practices:

Dren Bio is an equal opportunity employer. Employment decisions are based on merit and business needs. Dren Bio will not discriminate against any job applicant because of race, color, national origin, ancestry, gender, sexual orientation, age, religion, creed, physical or mental disability, gender identity, medical condition, pregnancy, marital status, veteran status, or any other characteristic protected by federal, state or local law.

Interested Applicants:

Please send resume and cover letter to cmc_careers@drenbio.com