Position:

Manager/ Sr Manager, TMF Operations

About the Company:

Dren Bio (the "Company") is a privately held, 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 drug discovery programs. The Company's first program surrounds DR-01, its 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 surrounds its Targeted Myeloid Engager and Phagocytosis Platform, a proprietary bispecific antibody-based technology that provides a novel mechanism of action to selectively engage myeloid cells for (1) targeted depletion of pathologic cells and other disease-inducing agents and (2) inducing localized immunostimulation. The engagement of antigen presenting cells has the potential to elicit a sustained, durable response.

Function: Clinical

Level: Manager/Sr. Manager

Location: Foster City, CA (Remote Candidates may be considered)

Reporting Manager: Head of Clinical Operations

About the Opportunity:

We are seeking an experienced and talented individual to oversee the electronic Trial Master File (eTMF) for all Dren clinical studies. The position requires a motivated, self-starter who works well in partnership with internal colleagues and external partners to ensure delivery of high quality clinical studies in a timely manner. Overall responsibilities will include support of Clinical Operations from study initiation through study closeout. The position can be remote based with some travel required.

Role and Responsibilities:

- Oversee TMF across all Dren studies and ensure inspection readiness at all times.
- Develop TMF plans, indexes, etc. for Dren clinical studies
- Perform periodic health checks of the TMF at study, country, and site-level
- Build out and manage internal TMF team as needed.
- Identify and implement eTMF configuration changes
- Manage eTMF user training, access, security, and permission requirements
- Update and maintain eTMF SOPs
- Ensure compliance with SOPs, Good Clinical Practice (ICH-GCP), and applicable regulatory requirements.
- Review IP release and activation packets for clinical sites
- Perform QC review of clinical study documents
- Create outstanding document reports
- Review Informed Consent Forms.
- Attend Investigator Meetings and other industry meetings as needed.
- Other duties as needed.

Education, Experience and Qualification Requirements:

- Bachelor's degree
- 7+ years direct experience within in clinical operations on Sponsor side
- Experience using Veeva Vault eTMF
- Knowledge of FDA and/or EMEA Regulations, ICH Guidelines, and GCPs governing the conduct of clinical trials.
- Detail-oriented, strong multi-tasking, and time management skills are required due to deadlines.
- Microsoft office suite (excel, powerpoint, word, outlook)
- Willingness to travel up to 20%
- Permitted to work in the United States

Core Competencies, Knowledge and Skill Requirements:

- A highly motivated self-starter
- Oncology experience
- A mature and self-assured team player who will work well with all other functional areas and can effectively interact with individuals at all levels of the organization and develop a cohesive relationship among the team
- Demonstrable/transformational leadership and interpersonal skills
- Ability to work under pressure and timeline constraints
- Ability to manage multiple competing priorities, being able to rapidly gather, assimilate and disseminate information on critical project components and milestones, and to translate to internal or external staff assigned to projects
- Detail focus with ability to manage technical/scientific aspects

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. The base pay range for this position at commencement of employment is expected to be between $120,000 and $150,000 per year. However exact base pay offered will be determined based on multiple individualized factors, including job-related knowledge, skills and experience and market location.

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 careers@drenbio.com