Position:

Associate/Senior Associate, Regulatory Affairs (Contract)

About the Company:

Dren Bio is a privately held, clinical-stage biopharmaceutical company pioneering the discovery and development of first-in-class antibody therapeutics for the treatment of cancer, autoimmune disorders, and other serious diseases. Leveraging our wholly owned technologies, we have built a robust R&D pipeline, including two clinical-stage candidates currently being evaluated across multiple ongoing clinical studies. Our lead clinical candidate, DR-01, is designed to induce antibody-mediated killing of a specific cell type implicated in a range of oncology and autoimmune indications. In addition, we have launched multiple programs from our proprietary Targeted Myeloid Engager and Phagocytosis Platform, a multispecific antibody-based technology engineered to selectively engage a novel phagocytic receptor expressed on myeloid cells (antigen presenting cells) for the targeted depletion of pathologic cells and other disease-causing agents. Data generated using the platform support its broad therapeutic potential, including initial programs focused on oncology, immunology, and neurology. Importantly, multispecific antibodies generated from the platform are specially designed to activate phagocytic mechanisms only in the presence of disease targets, potentially offering a superior safety profile compared to other immunomodulatory therapies. For more information, please visit our website at www.drenbio.com.

Function:

Regulatory Affairs

Level:

Associate/Senior Associate

Location:

San Carlos, CA (Hybrid candidates may be considered)

Reporting Manager:

Associate Director, Regulatory & Quality

About the Opportunity:

Dren Bio is seeking an experienced and talented individual who will be contributing to regulatory submissions and communications with various world-wide health authorities, maintaining Dren's regulatory archives and commitment trackers, interfacing with our external eCTD publishing team, and managing day-to-day operational aspects. This position requires a hands-on, self-starter who works well in partnership with internal colleagues and external partners and is familiar with the regulatory requirements for conducting global clinical studies.

Role and Responsibilities:

- Collaborate with team to ensure timely finalization of high-quality submissions that are compliant with applicable e-CTD requirements
- Under supervision, create routine submissions to health authorities.
- Under managerial supervision, serve as regulatory document and submission support for assigned projects.
- Interface with Regulatory eCTD publishing team regarding publishing of documents for regulatory submissions and archival of final published submissions
- Manage Regulatory submission trackers, archives, and commitment trackers.
- Work with Quality and other departments to ensure data accuracy and integrity relating to health authority submissions and reporting requirements.

Education, Experience and Qualification Requirements:

- Bachelor's degree in a scientific field (E.g. Clinical, Biological, Mathematical) is required; advanced degree is a plus.

- Minimum of 2 years in Regulatory Affairs in Biotechnology/Biopharmaceuticals.

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

Required Skills and Experience:

- Good background in biological/physical science and the ability to apply that knowledge to regulatory issues.
- Prior experience supporting regulatory submissions in pharmaceutical product development, particularly with investigational new drug applications (INDs) in the US, CTAs in Europe, Australia, and Asia.
- Good submission management skills and able to effectively work with team members to ensure complete and timely submissions to health authorities.
- Familiarity with health authority regulatory requirements and processes (E.g., ICH, CFR).
- The ability to be a productive team member, capable of making effective and knowledgeable contributions, and willingness to learn new skills.
- Advanced experience with Microsoft office tools, Adobe, and eCTD software.
- Experience reviewing published eCTD outputs for complex Regulatory submissions.
- Must be well-organized and capable of handling multiple priorities.
- Possess strong interpersonal skills that foster productive cross-functional relationships in development teams.

Interested Applicants:

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