Position:

Senior Manager, Regulatory Affairs

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:

Regulatory Affairs

Level:

Senior Manager

Location:

Foster City, CA (Remote candidates may be considered)

Reporting Manager:

SVP, Regulatory & Quality

About the Opportunity:

Dren Bio is seeking an experienced and talented individual who will oversee the writing, preparation and finalization of regulatory submissions and communications with various world-wide health authority. The position requires a hands on, self-starter who works well in partnership with internal colleagues and external partners. This person will also be responsible for providing strategic input pertaining to drug development issues and for advising on regulatory compliance matters.

Role and Responsibilities:

- Project team representative with responsibility for providing regulatory guidance/input on development issues.
- Serve as a liaison with regulatory authorities for assigned projects.
- Oversee timely writing, preparation, and finalization (including actively writing regulatory documentation) of scientifically valid/accurate submissions that are compliant to the applicable health authority requirement.
- Provide regulatory advice on development activities to ensure compliance with health authority law, regulation, and guideline.
- Manage submission archives on assigned projects.
- Work with Quality and other departments to ensure data accuracy and integrity relating to health authority submissions and reporting requirements.

- Contribute to strategic product development decisions in the context of applicable laws, regulations, and guidance from health authorities.
- Participate in corporate partnership efforts.

Education, Experience and Qualification Requirements:

- Bachelor's degree in Scientific field (E.g. Clinical, Biological, Mathematical) is required; advanced degree is a plus
- Minimum of 5 years in regulatory affairs in Biotechnology with experience in monoclonal or biologics

Core Competencies, Knowledge and Skill Requirements:

- Good background in biological/physical science and the ability to apply that knowledge to regulatory issues
- Prior regulatory submissions experience in biotechnology product development, particularly with investigational new drug applications in the US, Canada, Europe and Australia
- Experienced with regulatory agency interactions and in preparing teams for meetings with health authorities
- Good writing skills and able to effectively describe complex situations in regulatory documents
- The ability to a productive team member, capable of making effective, knowledgeable contributions
- Must be well-organized and capable of handling multiple priorities
- Proven ability in creative problem solving and the ability to eliminate roadblocks to development
- Possess a strong interpersonal skill that fosters a proactive approach to working cross-functionally on development teams

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 $147,000 and $172,000 per year. At Dren Bio, pay ranges are determined by role, level(s), and location. The range displayed in this job posting reflects the minimum and maximum new hire pay for candidates located across all United States job markets. Within the range, individual pay will be determined by work location and additional factors, including job-related skills, experience, and relevant education or training. During the hiring process, Dren Bio's Human Resources department can share more about the specific pay range based on the market location of the candidate.

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