Position:

Associate Director/ Director, Regulatory Affairs

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 Director/ Director

Location:

Foster City, CA (moving to San Carlos, CA Sep/Oct 2025)

Reporting Manager:

SVP, Regulatory Affairs

About the Opportunity:

Dren Bio is seeking an experienced and talented individual who will provide regulatory strategic guidance on development programs, as well as oversee the writing, preparation and finalization of regulatory submissions and communications with various world-wide health authorities. 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 advising on regulatory compliance matters.

Role and Responsibilities:

- Proactively develop and provide regulatory guidance on strategies for optimal drug development and marketing authorization in the United States and other identified regions.
- Contribute to team and corporate product development decisions in the context of applicable laws, regulations, and guidance from health authorities.
- Lead all regulatory communications with and submissions to the US-FDA and other identified health

authorities (eg, INDs/CTAs, expedited designations [eg, fast-track, breakthrough, prime], orphan drug applications, pediatric investigation plans, development/scientific advice, marketing applications).

- 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.
- Develop and maintain strong relationships with the FDA and other identified health authorities to foster close partnerships geared towards optimizing product development and registration.
- Contribute to establishing and administering internal regulatory policies and procedures to achieve best practices work processes.
- Stay abreast of newly issued regulatory laws and guidance as well as technical publications, articles, and abstracts to promptly identify possible impact or improvements to product programs.
- Participate in professional and industry organizations to follow regulatory trends, influence development of regulations and guidance, and develop relationships to represent the interests of the company.
- Work with Quality and other departments to ensure data accuracy and integrity relating to health authority submissions and reporting requirements.
- Participate in corporate partnership efforts.

Education, Experience and Qualification Requirements:

- Bachelor's degree in a scientific field (eg, Clinical, Biological, Mathematical) is required; an advanced degree is a plus.
- Minimum of 10 years for Associate Director or 12+ years for Director in regulatory affairs in Biotechnology or comparable experience.

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, 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 be 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 $170,000 and $220,000 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