

**Position:**

Senior Director/ Executive 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, dibotatug, 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](http://www.drenbio.com).

**Function:**

Regulatory Affairs

**Level:**

Senior Director / Executive Director

**Location:**

San Carlos, CA

**Reporting Manager:**

SVP, Regulatory Affairs

**About the Opportunity**

Dren Bio is seeking an experienced regulatory leader to provide strategic leadership for development programs and guide global regulatory strategy from clinical development through marketing application and approval. This role will serve as a senior regulatory partner to cross-functional teams, with particular responsibility for interactions with the U.S. Food and Drug Administration (FDA) and other global health authorities, for expedited-pathway strategy (including PRIME and Real-Time Oncology Review), and for the strategy, planning, preparation, and submission of Biologics License Applications (BLAs). The successful candidate will combine strategic judgment with a hands-on approach to regulatory execution and will work closely with Clinical Development, Clinical Operations, CMC, Quality, Safety, Biostatistics, Medical Writing, and other internal and external partners to advance development and registration objectives.

## **Role and Responsibilities**

- Lead and deliver global regulatory strategy for designated development programs, integrating clinical, nonclinical, CMC, safety, and other functional considerations into clear, dated regulatory plans and filing sequences.
- Provide proactive regulatory guidance to optimize drug development and marketing authorization strategies in the United States, Europe, and other identified regions.
- Lead FDA interactions, including development of meeting strategy, briefing materials, key messages, team preparation, meeting participation, and follow-up on agency feedback and commitments.
- Lead regulatory strategy, planning, and execution for BLA submissions end to end, including submission readiness, integrated cross-functional planning, content strategy, review, and responses to health authority questions through review and potential approval.
- Develop and execute expedited-pathway strategy, including requests for Fast Track, Breakthrough Therapy, orphan drug, and EMA PRIME designation; lead the preparation and submission of PRIME eligibility requests and manage the resulting enhanced EMA interactions.
- Evaluate and, where appropriate, lead strategy and planning for FDA Real-Time Oncology Review (RTOR) and related Oncology Center of Excellence programs (such as Project Orbis and Assessment Aid), including submission readiness for rolling, early data sharing with the agency.
- Lead interactions with global health authorities, including the EMA, MHRA, PMDA, Health Canada, and other regional regulators; guide scientific advice, Pediatric Investigation Plan/Pediatric Study Plan alignment, and regional filing strategy, and coordinate concurrent or staggered submissions across regions.
- Provide strategic oversight for regulatory submissions and communications, including INDs/CTAs and amendments, meeting requests and briefing packages, expedited program and designation requests, annual reports, and marketing applications (BLA, MAA, and others), as applicable.
- Anticipate regulatory risks, identify options and mitigation strategies, and communicate recommendations and implications to program teams and senior leadership.
- Interpret FDA and other health authority regulations, guidance, precedent, and evolving regulatory expectations and translate them into practical development and submission strategies.
- Partner closely with Clinical Development, Clinical Operations, CMC, Quality, Safety, Biostatistics, Medical Writing, and other functions to ensure regulatory requirements and agency feedback are incorporated into development plans and deliverables.
- Oversee the timely preparation and finalization of high-quality, scientifically accurate regulatory documents and submissions; contribute directly to strategic documents and critical submission content as needed.
- Build and maintain effective working relationships with the FDA and other relevant health authorities and represent Dren Bio in regulatory interactions in a clear, credible, and collaborative manner.
- Contribute to regulatory processes, standards, and ways of working that support submission quality, inspection readiness, and efficient execution as programs advance.
- Provide regulatory leadership, coaching, and mentorship to colleagues and project teams; management responsibilities may be included based on organizational needs and candidate experience.

## **Education, Experience and Qualification Requirements**

- Bachelor's degree in a scientific, life sciences, pharmacy, or related discipline is required; an advanced degree (MS, PharmD, PhD, or equivalent) is preferred.
- Minimum of 12+ years of progressive regulatory affairs experience in the biotechnology or pharmaceutical industry, with level and scope commensurate with Senior Director or Executive Director responsibilities.
- Demonstrated experience leading regulatory strategy for biologic products across clinical development, with significant direct experience interacting with the FDA and exposure to other global health authorities (e.g., EMA, MHRA, PMDA, Health Canada).
- Hands-on experience leading or playing a major regulatory leadership role in at least one BLA planning and submission process is required; experience carrying a BLA through health authority review to approval is strongly preferred.
- Direct experience developing and executing expedited-pathway strategy (Fast Track, Breakthrough Therapy, orphan drug, accelerated approval, and/or PRIME) is required; experience obtaining PRIME eligibility is strongly preferred.
- Experience with FDA Real-Time Oncology Review (RTOR) or other rolling and early-submission review programs is highly desirable, as is oncology development experience.

#### **Core Competencies, Knowledge and Skill Requirements**

- Deep knowledge of FDA regulations, guidance, and regulatory expectations for development and registration of biologic products, including expedited programs; working knowledge of ICH, EU (EMA/PRIME), and other relevant global regulatory frameworks.
- Proven ability to develop and communicate integrated regulatory strategies, evaluate regulatory precedent, and translate agency feedback into actionable development plans, including where precedent is limited or evolving.
- Strong BLA expertise, including regulatory strategy, submission planning, content and readiness oversight, cross-functional coordination, and management of health authority questions during review.
- Working knowledge of expedited and real-time review mechanisms, including PRIME, Breakthrough Therapy, RTOR, and Project Orbis, and the ability to determine when and how to pursue them.
- Demonstrated success leading FDA and other global health authority meetings and preparing cross-functional teams for high-impact health authority interactions.
- Ability to critically review complex clinical, nonclinical, CMC, safety, and statistical information and identify regulatory implications, risks, and opportunities.
- Excellent regulatory writing, communication, negotiation, and presentation skills, with the ability to communicate complex issues clearly to technical teams and senior leaders.
- Strong cross-functional leadership and influencing skills, including the ability to build alignment and drive decisions without relying on formal authority.
- Strategic and pragmatic problem-solving skills with sound judgment in ambiguous or evolving situations.
- Ability to manage multiple priorities and high-impact deliverables in a fast-paced biotechnology environment while maintaining quality and attention to detail.

#### **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 \$230,000 and \$280,000 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](mailto:careers@drenbio.com)