Position:

Director/ Senior Director, Medical Writing

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.

Function:

Regulatory Affairs

Level:

Director/ Senior Director

Location:

San Carlos, CA (remote candidates may be considered)

Reporting Manager:

SVP, Regulatory Affairs

About the Opportunity:

Dren Bio is seeking a highly motivated, well-organized, and skilled Director/Senior Director, Medical Writing to provide strategic and operational leadership across programs spanning early- and late-stage development. This role is responsible for delivering high-quality regulatory and clinical documents that support global development and registration strategies.

This individual will work closely with stakeholders in Clinical Development, Clinical Operations, Biostatistics, and other functional areas and manages medical writing service providers to develop Regulatory documents, including but not limited to NDA/MAA and eCTD submissions, clinical study protocols and clinical protocol amendments, clinical study reports, patient narratives, clinical development plans, IND submissions, integrated summary reports, , and Investigator Brochures, etc.

Role and Responsibilities:

- Prepare documents in accordance with internal SOPs as applicable, and relevant ICH and regulatory/industry guidelines.
- Critically analyze complex data and information and collaborate with clinical, medical, and biostatistics/data science teams to present data in clear, scientifically accurate documents. Ensure adherence to timelines.
- Lead cross-functional document reviews, resolve feedback, and drive documents to approval
- Plan and manage medical writing activities and resources across multiple programs

- Participate in and oversee vendors for the writing, QC editing, and confirmation of the scientific and medical accuracy of clinical and regulatory documents
- Work effectively with cross-functional teams by creating an atmosphere of openness and trust
- Provide support in development of submission-ready documents
- Represent department in audits and interdepartmental working groups

Education, Experience and Qualification Requirements:

- Bachelor's degree in life sciences or a related discipline is the minimum; advanced degrees (Master's, PharmD, or PhD) are highly preferred
- 10-12 years of medical writing experience, in biotech/pharmaceutical industry, including 5+ years in a leadership role supervising a medical writing team
- Proven leadership experience supporting INDs and at least one BLA or NDA submission

Core Competencies, Knowledge and Skill Requirements:

- Excellent writing ability with strong editorial and formatting skills
- Fluency in written and spoken English
- Self-directed and solution oriented with good problem-solving skills that allow analysis, synthesis, and compilation of data from a broad range of disciplines
- Extensive knowledge of FDA and ICH regulations and guidelines, as well as familiarity of AMA Style Guide and Chicago Manual of Style
- Strong proficiency in Word, Excel, PowerPoint, and other applications
- Experience working in small to mid-sized biotech or fast-growth environments with novel oncology and autoimmune therapeutics
- Strategic thinking, scientific rigor, strong leadership and team development with high attention to detail and quality focus
- Strong time-management skills to handle multiple concurrent projects under tight deadlines
- Ability to manage multiple priorities in a fast-paced environment
- Experience managing vendors

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 $190,000 and $240,000 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