Job Title: Medical Writer

Reports to: Chief Medical Officer

FLSA /Pay Grade: Exempt

Why Artiva

Over the past decade we have seen stunning advances in the cellular immunotherapy therapy field in particular, with dramatic rates of clinical response in hematological malignancies, and rapid evolution of our understanding of factors that could extend this success to solid tumors. However, these transformative therapies are often accompanied by severe and potentially life-threatening toxicities, and patient access is limited by such factors as complex, time-consuming patient-specific manufacturing, variable product quality, and cost.

Our Mission

At Artiva, our mission is to deliver highly effective cell therapies that are also safe and immediately available and accessible to any patient who may benefit.

Position Summary: Reporting to the Chief Medical Officer, the Medical Writer will support development teams and be responsible for writing and overseeing the preparation of clinical and regulatory documents. At this stage of Artiva's evolution this position is a sole contributor and therefore requires someone who will "roll up their sleeves" to get the work done, but who also has the desire and capability to plan and build out the medical writing group when needed.

Role & Responsibilities

- Lead efforts to author documents including clinical study protocols, Patient Informed Consent Form templates, Investigator Brochures, lab manuals, annual reports, clinical study reports, regulatory briefing documents, and clinical sections of regulatory submissions (IMPDs, INDs, and CTAs).
- Write, edit and collaborate with clinical program team members on a variety of clinical and regulatory documents.
- Ensure efficient document management as well as consistent style of presentation to maintain quality and ease of review across multiple documents assembled in a regulatory dossier.
- Develop standards and best practices for the process of document review, completion, and approval, ensure adherence to regulatory requirements and industry standards, and consistency with America Medical Writing Standards, where applicable.

- Develop writing standards, including any relevant document templates and style guides; update templates and style guides as needed.
- Review, edit, and ensure quality of documents or sections of documents prepared by functional area representatives, as required, and ensure adherence to established standards.
- Ensure documents produced are of the highest quality and completed per timelines and are compliant with SOPs, ICH/GCP/regulatory guidelines and company goals.
- Provide guidance on clinical data being considered for presentation and/or publication to ensure alignment with scientific strategies and corporate goals.
- Plan, write, edit, and review documents in collaboration with the project teams (e.g., conference abstracts, poster/oral presentations/manuscripts).
- Coordinate and prioritize multiple project deadlines in a fast-paced environment.
- Create, monitor, and maintain timelines across multiple projects.
- Develop overall quality review of documents in compliance with established standards and best practices.
- Lead strategic discussions to ensure aligned messaging throughout clinical and regulatory documents.
- Engage and manage externally contracted writing staff as required.

Experience, Education and Specialized Knowledge and Skills

Must thrive working in a fast-paced innovative environment while remaining flexible, proactive, resourceful, and efficient. Ability to manage multiple projects and timelines through outsourced or internal teams. Excellent interpersonal skills, ability to develop important relationships with key stakeholders, conflict management and negotiation skills, ability to analyze complex issues to develop relevant and realistic plans and recommendations. Demonstrated ability to translate strategy into action. Excellent analytical and writing skills, ability to communicate complex issues in a simple way, and ability to orchestrate plans to resolve issues and mitigate risks.

Competencies

- Decision Making
- Time Management
- Strategic Thinking
- Medical Writing
- Leadership & Team Development
- Risk Management
- Flexibility and Prioritization
- Implementing Plans
- Proficient in English Grammar and Spelling
- Mastery of Word Processing Software

Attributes

- Honesty/Integrity
- Self-starter
- Creative/imaginative
- Self-controlled
- Effective communicator (verbal and written)
- Forward thinking
- Confident
- Intuitive

- Positive
- Self-motivated
- Collaborative
- Detail oriented
- Committed
- Mentally agile
- Transparent

We look for talented, entrepreneurial people who share our values.

We are called to put the **safety** of our patients and employees first, and to act with **integrity** and the highest ethical standards. To achieve our mission, we must collaborate across the Company at all levels, and we must hold ourselves and our teams **accountable** for delivering the progress we commit to, on the timelines we set. We embrace **diversity**, we include people and their ideas, and we aspire to **excellence** by listening, understanding, sharing and responding. We want you to be fully **engaged**, to develop personally and professionally through this chapter in your life, and to have **fun** along the way.

Artiva Biotherapeutics is an equal opportunity employer that is committed to providing a work environment free of harassment and discrimination based upon a protected category, as well as an environment free from retaliation for protected activity.

Benefits

- The opportunity to work with a team of highly experienced professionals from clinical to regulatory to CMC to research
- To be part of building a company on the cutting edge of cell therapy that may be a game changer to patients in a culture that is entrepreneurial, highly collaborative and innovative
- Competitive compensation, including bonus
- Equity program
- Health and welfare benefits – Medical, Dental, Vision, Life, 401K, EAP

To apply, please send cover letter and resume/CV to: careers@artivabio.com.