Position: **Director, Medical Writing**

Reports to: **Executive Director & Head of Regulatory Science Communications**

Location: **Brisbane, CA**

Summary

The Director, Medical Writing will be responsible for overseeing the development and finalization of key clinical and regulatory documents across therapeutic areas and throughout the product lifecycle.

Specific Responsibilities:

- Lead and contribute to the development of clinical and regulatory documents such as clinical protocols, clinical study reports, investigator brochures, DSURs, briefing packages, INDs and amendments, BLA/MAA documents, and regulatory responses according to company standards, processes, and timelines
- Participate on cross-functional teams and collaborate with team members to develop strategy and finalize project timelines
- Identify resources for projects; recruit/oversee consultants as needed
- Provide managerial support to one or more employees with overall responsibility of leading, training, and mentoring for effective performance
- Mentor junior medical writers, editors, and other team members
- Critically review project work and training materials/guidelines generated by team members
- Coordinate with Regulatory Science Information to execute scientific review processes.
- Lead SOP development and review; implement work process improvements
- Keep up-to-date with professional information and technology through workshops and conferences and ensure the appropriate transfer of that information to the department.
- Other duties as assigned

Qualifications / Requirements:

- Bachelor's degree in a science discipline or healthcare-related field. Advanced degree strongly preferred
- 10+ years of experience as a clinical/regulatory writer within the biotechnology or pharmaceutical industry required; freelance or closely related experience may be taken into consideration
- 5+ years of manager experience
- Expert knowledge of the drug development process and regulatory requirements for documents including applicable regulations, ICH guidance, and GCP standards
- Expert skills in researching, writing, editing, reviewing, and managing clinical and scientific content
- Able to manage multiple projects in a fast-paced environment with challenging deadlines and rapidly changing priorities
- Good judgment and willingness to adapt working style and work product as required while adhering to quality standards
- Record of collaborative multidisciplinary teamwork and problem solving; help facilitate cross-functional team agreement and complete projects without authority
- Highly proficient in organization and project management skills

- Expert knowledge of AMA style, medical terminology, and clinical data analysis
- Expert knowledge and skills using Microsoft Word to generate complex document
- Exceptional attention to detail, goal-oriented with assigned tasks, and self-motivated
- PC literacy required; MSOffice skills (Outlook, Word, Excel, PowerPoint)
- Strong team-building skills
- Excellent interpersonal and influencing skills; ability to negotiate well and build good relationships with coworkers
- Professional and friendly demeanor, flexible, accommodating

Preferred Experience, Special Skills, Knowledge:

- AMWA member with certificate a plus
- BELS certification a plus

About Aimmune Therapeutics, Inc.

Aimmune Therapeutics is a clinical-stage biopharmaceutical company founded to address the unmet medical need in food allergy, which currently has no approved treatments. Our mission is to improve the lives of people with food allergies, based on our proprietary desensitization treatments in development. Aimmune's recently announced positive top-line data from its pivotal Phase 3 PALISADE trial for AR101, the company's lead investigational drug for peanut allergy. Headquartered in the heart of San Francisco's biotechnology hub, Brisbane, California, Aimmune has additional offices in the Kings Cross area of London, and in Raleigh, North Carolina.

Qualified candidates should forward a resume and cover letter, including a statement of interest, availability, and experience to Human Resources (careers@aimmune.com) with the job title in the subject line.

Aimmune Therapeutics is an Equal Opportunity Employer.

Principals only; no recruiters please.