Position: **Regulatory Science Communications Associate**

Reports to: **Director, Regulatory Science Information**

Location: **Brisbane, CA**

Summary

The Regulatory Science Communications Associate will be responsible for ensuring the scientific quality of information in key clinical and regulatory documents prepared for external release such as submissions to global regulatory authorities.

Specific Responsibilities:

- Perform scientific information review of key complex documents such as briefing packages, summaries for regulatory filings (IND, BLA/MAA, IMPD), clinical protocols/amendments, investigator brochures/updates, clinical study reports, and other documents as assigned according to timelines and company standards and processes
- Ensure that data and information in key complex documents are accurate, consistent with source documents, internally consistent, and meet internal standards of style and quality
- Facilitate the scientific information review process with cross-functional team
- Contribute to the improvement of processes for scientific information review
- Participate in SOP development related to scientific information review
- Other duties as assigned

Qualifications / Requirements:

- Bachelor's degree in a science discipline; advanced degree in a science discipline preferred
- Minimum 2 years of experience within the biotechnology or pharmaceutical industry; closely related experience may be taken into consideration
- Knowledge of the drug development process, regulatory requirements, and general science concepts
- Direct involvement at an intellectual and analytical level in the quality review of key documentation for drug development, preferably across multiple disciplines in a biopharmaceutical company
- An understanding of medical terminology, and clinical data analysis and reporting preferred
- Proven attention to detail and ability to identify discrepancies and inaccuracies (factual, numerical, and typographical) in dense, complex documentation
- Able to perform calculations to verify data with no direct source

- 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
- Strong written and oral communication skills
- Good interpersonal skills; ability to negotiate well and build good relationships with coworkers; ability to collaborate effectively in a dynamic environment
- Goal oriented with assigned tasks, self-motivated
- Professional and friendly demeanor, flexible, accommodating

Preferred Experience, Special Skills, Knowledge:

- Clinical operations, quality assurance, or laboratory experience a plus
- Knowledgeable of ICH E6 requirements 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.