Position: **Manager, Regulatory Affairs**

Reports to: **Head of North America Regulatory Affairs**

Summary

The Manager, Regulatory Affairs provides key support to the Regulatory Affairs department. This position has primary responsibility for coordination and assembly of regulatory documents for review and submission to health authorities (primarily the FDA, other regulatory agencies as needed). The Manager, Regulatory Affairs will be responsible for maintaining and updating archival copies of health authority submissions (e.g. IND, BLA, and MAA). The Manager, Regulatory Affairs will ideally have a working knowledge of regulatory requirements specific to key regions such as the US, Canada, and EU, and have a general awareness of current global trends in Regulatory Affairs.

Specific Responsibilities:

The primary job functions include, but not limited to the following:

- Under the direction of a senior Regulatory staff member, prepare, compile review, and submit documents for the company, including but not limited to initial INDs/CTAs/BLAs and amendments or supplements
- Assist regulatory management and project teams in the implementation of regulatory plans and timely delivery of regulatory documentation
- Develop, maintain, and communicate timelines for regulatory submissions
- Participate in the review of critical documents such as: protocols, ICFs, IBs, CSRs, DSURs, etc to ensure they are compliant with relevant regulations and guidance (e.g. ICH, FDA, EMA, etc.) prior to submission
- Coordinate with Regulatory Operations to gather and assemble information necessary for submissions to health authorities in accordance with regulations and guidelines
- Maintain databases of regulatory information, submissions and correspondence
- Follow general instructions to complete projects while independently planning daily work to complete time sensitive assignments
- Review, write and present guidelines and SOPs as needed to support high quality submissions and assure adherence to regulatory requirements
- Maintain current knowledge of applicable US and global regulations, guidance, and standards for drug development and product registration

Qualifications / Requirements:

- A minimum of a BS in life sciences with at least 5 years of experience in Regulatory Affairs in the biotechnology or pharmaceutical industries (an equivalent combination of education and experience may be considered)
- Understanding of the drug development process and knowledge of global guidance and regulations
- Has successfully supported health authority submissions and critical projects while maintaining agreed timelines
- Previous experience with IND filings or maintenance required and previous experience with eCTD formatted submissions and NDA or BLA filings desirable

Special Skills / Knowledge:

- Excellent oral and written communication skills
- Time management skills are essential
- Demonstrated ability to work effectively with cross-functional teams e.g. research, clinical, and CMC teams
- Ability to implement regulatory plans and strategies and proactively identify risks.
- Ability to work on multiple tasks to meet company objectives
- Strong attention to detail
- Knowledge of 21 CFR and FDA, ICH, GCP, GMP, and global guidelines
- Excellent Computer Skills – MS Word, Excel, Power Point, and document management software/system

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 lead investigational drug for peanut allergy, AR101, is in Phase 3 clinical testing in North America and Europe. 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.