Position: **Senior Manager, Regulatory Affairs**

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

Summary

The Senior Manager, Regulatory Affairs works independently or with limited oversight to provide key support to the Regulatory Affairs department. The primary responsibilities for this position include planning, coordination, and assembly of regulatory documents for review and submission to health authorities (i.e., FDA, Health Canada, and other regulatory agencies, as needed). The Senior Manager, Regulatory Affairs will have demonstrated the ability to independently apply knowledge of regulatory requirements (specific to key regions such as the US, Canada, and/or EU) to their daily work and manage critical projects as part of an interdisciplinary team. The Senior Manager, Regulatory Affairs is responsible for managing, tracking, and maintaining submission to health authorities (e.g. IND, BLA, and MAA).

Specific Responsibilities:

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

- Independently or with limited oversight plan, 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 development and implementation of regulatory strategies and plans.
- Develop, maintain, and communicate timelines for regulatory submissions to ensure timely delivery of regulatory documentation.
- 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 appropriately plan and finalize submissions to health authorities in accordance with regulations and guidelines.
- Maintain databases of regulatory information, submissions and correspondence.
- Independently plan 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 7 years of experience in Regulatory Affairs in the biotechnology or pharmaceutical industries (an equivalent combination of education and experience may be considered).

- Demonstrated experience leading eCTD formatted submissions for biologics and/or drugs e.g. INDs, NDAs/BLAs, MAAs, annual reports, amendments and supplements.
- Previous experience with NDA or BLA submissions desirable.
- Experience in management of all components of regulatory submissions (including chemistry, manufacturing and controls) is a plus.
- Detailed understanding of the drug development process, FDA/EMA guidance and regulations, and knowledge of global guidance.
- Has successfully coordinated and supported responses to health authorities and critical submission projects while maintaining agreed timelines.
- High attention to detail, ability to work on multiple projects with tight deadlines and able to work independently.
- Demonstrates creative approach to problem solving; with a demonstrated track record of being results driven.

Special Skills / Knowledge:

- Excellent oral and written communication skills and time management skills essential.
- Demonstrated ability to work effectively with and/or lead cross-functional teams e.g. research, clinical, and CMC teams.
- Ability to develop regulatory plans and strategies while proactively identifying 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.