Position: **Senior Manager / Associate Director Regulatory Operations**

Reports to: **Head of Regulatory Science Communications**

Location: **Brisbane, CA**

Summary

The Senior Manager/Associate Director, Regulatory Operations will have overall accountability for the delivery of regulatory submissions in compliance with global health authority requirements. The position will oversee Regulatory Operations personnel and external vendors responsible for ensuring timely submissions of the highest quality, such as initial INDs, global marketing applications, briefing packages, annual reports, safety reports, amendments, and supplements.

Specific Responsibilities:

- Lead the Regulatory Operations team by developing, communicating, and building consensus for programs and goals that support team and company objectives
- Manage, mentor, train, and retain Regulatory Operations personnel
- Develop, implement, and maintain tools and processes to maximize efficiency, cost, and quality of regulatory submissions and regulatory information management systems
- Manage various systems and tools (eg, publishing, eCTD viewer, templates, Acrobat plug-in tools, ESG)
- Conduct final review of published submissions to ensure consistency and compliance with regulatory requirements
- Oversee regulatory information management tasks including file transfer, storing, tracking, and archiving of regulatory submission documentation
- Serve as the business lead in partnership with IT on projects for implementing or upgrading systems and technologies to ensure compliance with health authority requirements, industry/company standards, and business processes
- Develop best practices and collaborate with departmental staff to ensure adherence to infrastructure standards. Evaluate and optimize the effectiveness of current work processes and operational plans
- Lead or coordinate the development of Regulatory Operations processes (SOPs, work instructions, guidelines, templates) for preparing submissions and regulatory information management
- Maintain the Aimmune Styles Template and manage complex Word document formatting including complicated tables and graphs. Ensure the use of company style guide for regulatory submission documents
- Provide annual budgeting, headcount, IT, and consulting forecasts. Evaluate the need for additional resources based on projected workload
- Other duties as assigned

Qualifications / Requirements:

- Bachelor's degree or equivalent combination of education and work experience
- At least 5 years of experience in the pharmaceutical industry, including submissions of original eCTD marketing applications (BLA, NDA, MAA) and IND applications
- Experience leading, training, and mentoring Regulatory Operations personnel
- Proficient using eCTD software, MS Office Suite, Adobe Acrobat and plug-in tools, and publishing systems
- Expert-level Word formatting skills
- Demonstrated organizational skills, excellent oral/written communication and interpersonal skills, and attention to detail
- Willing to work with shifting timelines and rapid changes in project scope and priority

Preferred Experience, Special Skills, Knowledge:

- Experience compiling IND, NDA/BLA eCTD submissions in the US; international submissions experience is a plus
- Knowledgeable of ICH, 21 CFR Part 11, and electronic submission requirements and processes

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.