**Position:** **Sr. Manager, EU Regulatory Affairs**

**Reports to:** **VP, Regulatory Affairs and Quality, Europe**

**Summary**

The Senior Manager, Regulatory Affairs provides key support to the global Regulatory Affairs team. This position has primary responsibility for assembling regulatory documents for review and submission to EU Competent Authorities and other regulatory agencies (as requested).

**Specific Responsibilities:**

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

- Under the direction of the VP, Regulatory Affairs and Quality, Europe, compile, prepare, review, and submit regulatory submission documents for the company in the EU, including but not limited to initial CTAs and CTA amendments, PIPs, annual reports, national and EMA Scientific Advice.
- Support MAA preparation activities.
- Gather and assemble information necessary for submissions in accordance with regulations and relevant guidelines. Perform data integrity check on all submissions to regulatory agencies.
- Assist regulatory management and subject matter experts in briefing documents generation and coordination of responses to requests or questions from regulatory authorities.
- Work closely with colleagues in other functional areas to ensure timely approvals of submissions and ensure compliance with appropriate EU guidelines.
- Maintain regulatory database of regulatory information and submissions.
- Review, write and present guidelines and SOPs that support high quality submissions and assure adherence to regulatory requirements.
- Keep abreast of changing regulations and guidelines on drug development and registration and disseminate intelligence on EU regulatory matters to management and regulatory colleagues.
- Follow general instructions to complete projects, plan and organize workday to complete time sensitive assignments.
- Work closely with US Regulatory Affairs to ensure an integrated, global approach to regulatory affairs.

**Qualifications / Requirements:**

- Bachelor's degree in Science with broad professional experience gained from previous EU Regulatory Affairs roles.

**Special Skills / Knowledge:**

- Excellent oral and written communication, interpretive and interpersonal skills, including time management skills
- Strong attention to detail
- Knowledge of EU regulatory guidelines
- Ability to work on multiple tasks to meet company objectives
- Demonstrated ability to coordinate and work effectively with cross-functional teams
- Excellent Computer Skills – MS Word, Excel, Power Point, and document management software/system
- Previous experience with CTA filing and maintenance and MAA submission support required

**About Aimmune Therapeutics, Inc.**

Aimmune Therapeutics is a clinical-stage biopharmaceutical company with headquarters in Brisbane, California. This position is based in Aimmune's EU office in London, UK. The company is developing desensitization treatments for food allergies with the lead product, AR101 currently in Phase 3 studies in North America and Europe. For more information, please visit www.aimmune.com.

Aimmune Therapeutics offers a competitive compensation and benefits package.

Aimmune Therapeutics is an Equal Opportunity Employer.

**Qualified candidates should forward a CV 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.**

Principals only; no recruiters please.