Position: **Director, Regulatory Affairs (EU)**

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

Summary:

The Director, EU Regulatory Affairs provides key support to the global Regulatory Affairs team. This position has primary responsibility for providing input into 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 Marketing Authorisation (MA) applications, PIPs, annual reports, national and EMA Scientific Advice and MA variations
- Support MAA preparation and maintenance activities, particularly those related to clinical aspects of the product portfolio
- Gather and assemble information necessary for regulatory submissions in accordance with applicable legislation and relevant guidelines. Identify project issues and develop alternative strategies. Perform data integrity checks 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
- Develop and implement a process for label development and management in the EU and other applicable territories
- Provide oversight of regulatory activities in affiliate countries, as needed
- Work closely with colleagues in other functional areas to ensure timely approvals of submissions and ensure compliance with appropriate EU guidelines
- Contribute to 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, as required
- Support post approval commercial activities, including contribution to advertising and promotional material review and approval, as required.
- Work closely with US Regulatory Affairs to ensure an integrated, global approach to regulatory affairs
- Follow general instructions to complete projects and plans and organize workday to complete time sensitive assignments on target

Qualifications / Requirements:

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

Preferred Experience, Special Skills, Knowledge:

- Excellent oral and written communication, interpretive and interpersonal skills, including time management skills
- Strong attention to detail and highly organized
- Good knowledge of EU regulatory guidelines
- Ability to work on multiple activities and deliver tasks in line with 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 MAA filing and maintenance for new active substances and MAA submission support, particularly as it relates to clinical and labelling aspects of regulatory submissions
- Fluent in English. Knowledge of other European languages also beneficial

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.