Position: **Associate Director, Quality Assurance, Europe (GMP)**

Reports to: **Vice President, Quality Assurance**

Location: **Europe**

Summary

The Associate Director of Quality Assurance, Europe will play an essential role in the QA oversight of GMP activities to ensure clinical and commercial products are manufactured and tested in accordance with cGMP.

This position will report to VP Quality Assurance and be responsible for ensuring that all manufacturing campaigns are performed in compliance with Aimmune's Global Quality Systems, FDA guidelines and regulations, and European guidance and regulations. The position is also responsible for supporting internal and external audit plans and activities, and ensuring GMP-related Quality Systems are EU and/or country specific compliant across Aimmune Therapeutics, Inc.

Specific Responsibilities:

- Ensure European requirements for manufacture, control and supply of investigational and commercial product for European markets are identified and implemented in the Quality Management System, specifically for GMP QA in accordance with applicable regulatory requirements and Aimmune policies
- Ensure all therapeutic materials are manufactured and supplied under EU GMP conditions, act as Aimmune QA contact person for various manufacturing, packaging, labeling, and distribution activities with CMOs in the EU
- Oversee EU clinical trial and commercial materials manufactured or packaged by CMOs including batch record review, release, and disposition associated with Qualified Person certifications; and closure of OOSs, OOTs, NCMRs, CAPAs and deviations for each lot of material manufactured
    - Support establishment of new analytical testing and packaging facilities in the EU via Third Party vendors and provide oversight to ensure all QA related activities are identified and completed on time and in accordance with GMP and regulatory requirements
    - Support reviews for commercial labelling process in the EU from a QA/GMP perspective
- Conduct routine audits for CMOs and when necessary For Cause audits. Track CAPAs through closure, as applicable
- Provide cGMP QA guidance to the CMC, regulatory and Supply Chain departments based on analysis and interpretation of updates to EU GMP regulations to assure best practices
- Support the administration of Aimmune's training program. Conduct and document cGMP training, including EU cGMP training for Aimmune employees as required
- Report GMP or Quality Systems deficiencies to QA management

- Support preparation, coordination, and management of regulatory agency inspections, including PLI inspections and routine GMP inspections as needed
- Provide EU Quality representation in CMC team meetings

Qualifications / Requirements:

- B.S. degree in a scientific discipline
- 8-10 years of experience working within the CMC quality environment in the pharmaceutical or biotechnology industry, with specific experience in GMP quality assurance, auditing and GMP regulations
- Comprehensive understanding of EU QP requirements for batch testing and release for investigational and commercial pharmaceutical products
- Comprehensive working knowledge of EU, US and key international regulations pertaining to GMP for investigational and commercial pharmaceutical products
- Complete and thorough understanding of regulatory GMP compliance requirements for US FDA and European Union
- Auditor training or certification
- Prior experience in regulatory inspections
- Travel 15% to 20%

Preferred Experience, Special Skills, Knowledge:

- Results and goals oriented
- Excellent written and oral communication skills
- Accuracy and attention to detail
- Excellent cross-functional team participation skills
- Ability to effectively prioritize
- Outstanding problem-solving qualities
- Ability to grasp new technologies

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 recently announced positive top-line data from its pivotal Phase 3 PALISADE trial for AR101, the company's lead investigational drug for peanut allergy. 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.