Position: **Associate Director, Quality Assurance (Commercial)**

Reports to: **Director, CMC Quality Assurance**

Location: **Brisbane, CA**

Summary

The Associate Director Quality Assurance commercial lead will play an essential role in developing and managing the GMP QA program to ensure that materials made for commercial supply and distribution plus stability, are manufactured in accordance with cGMP regulations and European manufacturing guidelines.

This position will be responsible for ensuring that all manufacturing campaigns are performed in compliance with Aimmune's procedures and protocols, FDA guidelines and regulations, and European guidance and regulations. The position is also responsible for the development of internal and external audit plans and activities, providing cGMP training as applicable, and the development and maintenance of GMP-related quality systems across the company globally. This position leader will also be involved with any tech transfer QA activities and well as change controls related to overseeing our Contract Manufacturing Organizations (CMOs).

Specific Responsibilities:

- Establish and maintain a Quality Management System, specifically for commercial GMP QA in compliance with applicable regulatory requirements (US and OUS), and company policies
- Ensure all commercial materials are manufactured under GMP conditions, act as Person in Plant when necessary at various manufacturing, packaging, labeling, and distributing CMOs
- Review, approve, and release materials manufactured by CMOs via batch record review, release, and disposition. May include clinical batches as applicable
- Follow and manage trending of all OOSs, OOTs, NCMRs, CAPAs and deviations for each lot of commercial materials manufactured
- Conduct routine audits as applicable for commercial CMOs and when necessary For Cause audits. Report, follow and help to correct any non-conforming issues found in the audit processes
- Work with commercial CMOs to create, and keep current, quality agreements, technical agreements and method transfer processes
- Provide cGMP QA guidance to the CMC and Supply Chain departments based on analysis and interpretation of updates to GMP regulations to assure best practices as related to commercial QA activities
- Conduct and document cGMP training for company employees as required
- Report significant manufacturing deficiencies to QA management
- Support preparation, coordination, and management of regulatory agency inspections, including PAI inspections and routine GMP inspections as needed
- Provide quality oversight 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 working knowledge of local, state, federal, and international regulations pertaining to GMP, and European manufacturing requirements
- Complete and thorough understanding of regulatory compliance requirements for US FDA, and European Union
- Auditor training or certification
- Prior experience in regulatory inspections
- Travel 25% to 30%

Preferred Experience, Special Skills, Knowledge:

- Results and goals oriented
- Ability to effectively prioritize
- Excellent written and oral communication skills
- Accuracy and attention to detail
- Excellent cross-functional team participation skills
- 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.