Position: **Manager, Quality Assurance**

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

Summary:
This position's main responsibility is to provide Quality oversight of cGMP operations performed for Aimmune at Contract Manufacturing Organizations (CMOs) and/or Contract Testing Labs (CTLs) per the global regulatory requirements. Additional responsibilities may include conducting internal/external audits and participate in inspection readiness activities. This position provides Quality recommendations and guidance to project teams and manages other compliance duties as assigned.

Specific Responsibilities:

- Provide Quality oversight and leadership for cGMP activities related to Aimmune products produced at CMOs/CTLs
- Work directly with operating entities (internal and CMOs/CTLs) to ensure that clinical drug substance and drug products meet all required quality standards and specifications or are appropriately investigated
- Provide effective QA support for the manufacturing and disposition of clinical drug product lots
- Review and approve the CMO/CTL Specifications, Test Methods, Analytical Method Validation Protocols/Reports and Stability Protocols/Reports as assigned
- Work with CMOs/CTLs to ensure that policies at CMOs/CTLs adhere to cGMPs and regulatory requirements of FDA, EMA and other regulatory agencies, as required
- Ensure that Quality policies and practices at CMOs/CTLs adhere to approved quality agreements, monitor and provide corrective action recommendations to compliance issues and/or observations as they arise. Manage and coordinate process monitoring and continuous improvement initiatives as per cGMP requirements, as required
- Provide support and ensure CMOs/CTLs achieve the appropriate levels of compliance and develop plans to ensure on-going performance is maintained
- Facilitate resolution of quality issues in a timely manner. Coordinate communication with contract manufacturers and internal cross functional teams for quality issues
- Establish or revise assigned internal SOPs/Guidelines applicable to internal functions as well as outsourced functions to ensure compliance to cGMP
- Ensure compliance with the Quality Systems such as change control, quality investigations, and CAPA resolutions. Management of assigned QA operation tasks in accordance to SOPs
- May assist with review of regulatory filings, providing input into answering questions from health authorities, and providing input into presentations of materials during regulatory inspections/partner audits, as applicable
- Lead and perform QA audits/inspections (internal and external) as assigned
- Lead and represent QA in multi-departmental meetings & project teams

- Manage, oversee, develop and guide direct reports, if applicable, and/or contract support personnel
- Maintain current knowledge of industry standards and regulatory requirements for products developed or manufactured by Aimmune, techniques/approaches and systems utilized at Aimmune
- Other duties as assigned by the Management

Qualifications/Requirements:

- Bachelor of Arts/Sciences (BA/BS) degree, or higher, in a technical discipline (physical, engineering, chemical or biological sciences) is required
- 5+ years' experience in a cGMP regulated environment, with exhibited knowledge or proficiency in Quality Assurance
- Organizational and management skills to communicate to multi-discipline project groups.
- Ability to speak, present data, and defend approaches in front of audiences and inspectors
- Ability to comprehend technical information and regulatory expectations.
- Experience and participation in regulatory inspections presenting departmental functions in audits or regulatory inspections
- Proficiency with Office software applications, including MS Word, MS Excel, MS Project, MS Power Point
- Proficiency with technical summary report reviews required, with exceptional organizational attention to detail
- Knowledge of industry standards, guidance documents, and global regulatory requirements from Phase I to Phase III is required
- Training in project management is plus
- Ability to utilize computer to perform tasks

About Aimmune Therapeutics, Inc.

Aimmune Therapeutics is a clinical-stage biopharmaceutical company located in Brisbane, California, in the biotechnology hub south of San Francisco. The company is developing desensitization treatments for food allergies and is currently in Phase 3 trials for its lead product, for the treatment of peanut allergy, since early 2016. 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 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.

Principals only; no recruiters please.