Position: **Manager Clinical Quality Assurance (CQA) GCP Compliance**

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

Location: **Brisbane, CA**

Summary

The Clinical Quality Assurance (CQA) Manager will support the implementation and management of the Quality Assurance activities across multiple studies, and/or countries. The CQA Manager will utilize audit and inspection intelligence and risk mitigation plans to assure adherence to GCP in conduct of clinical trials, the quality and integrity of generated data, and the rights and welfare of subjects/patients.

The CQA Manager position is responsible for the execution of the global Quality Assurance (QA) audit activities, for Good Clinical Practice (GCP) oversight, and for assuring the compliance of studies with Aimmune Therapeutics or Clinical Research Organization (CRO) Standard Operating Procedures (SOPs), Policies, and all applicable worldwide regulations and guidelines (e.g. US FDA, EU Directives, ICH, and National regulations). This position reports directly to the Associate Director CQA.

Specific Responsibilities:

- Represents QA and provides QA guidance for project/study teams with participation in the applicable forums, providing GCP compliance input and guidance to customers, to achieve continuous quality improvement and effective quality controls
- Interfaces with relevant stakeholders, including regulatory, clinical and development sub-teams, as appropriate to provide Good Clinical Practice, and QA compliance expertise
- Ensures appropriate and timely escalation of quality issues, including potential misconduct or issues of significant deviation with projects/products
- Participates in the development of the GCP risk assessment and identification of areas to be audited
- Conducts QA audits (Investigator Site, Vendor, Internal process, For-cause, and directed/complex audits), generates audit reports, communicates results to the relevant QA management and external relevant stakeholders, and interacts with various teams to ensure corrective and preventative actions are taken to bring QA observations to closure as applicable

- Participates in the development/enhancement of QA procedures, guidance documents and audit tools to ensure QA consistency
- Provides GCP training, Mock Inspection preparation and support as needed
- Promotes GCP Compliance across the organization to meet appropriate corporate and department goals

Qualifications / Requirements:

- Bachelor's degree in a scientific discipline or equivalent qualification
- 5-7 years specific experience in GCP quality assurance auditing and compliance advice
- Comprehensive working knowledge of GCP related regulatory requirements US FDA, EU Directives and ICH guidelines
- Auditor training or certification a plus
- Prior experience in regulatory inspections preferred
- Travel approximately 25%

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, AR101 for peanut allergy, is in Phase 3 clinical testing in North America and Europe. The company also plans to begin clinical testing of its investigational drugs for egg allergy and walnut allergy. Headquartered in Brisbane, California – the heart of San Francisco's biotechnology hub – 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.