Position: **Manager, Clinical Quality Assurance (CQA) GCP EU**
(Level 2, Quality Assurance)

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

Location: **London, UK**

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
- Assists in the compliance checks of staff training

Qualifications / Requirements:

- Bachelor's degree in a scientific discipline or equivalent qualification
- Comprehensive & specific experience in GCP quality assurance auditing and compliance advice
- Comprehensive working knowledge of GCP related regulatory requirements EU Directives, US FDA, and ICH guidelines
- Auditor training or certification a plus but not essential
- Prior experience in regulatory inspections preferred
- Another Western EU language advantageous but not essential
- This role will involve EU and NA travel

Preferred Experience, Special Skills, Knowledge:

- Previous Quality Assurance GCP or Regulatory role in small pharma, small CRO or Small Biotech
- Excellent interpersonal and communication skills (written and verbal) across a wide range of disciplines
- Proven understanding of all elements of the clinical trial process
- Ability to communicate diplomatically and to work efficiently in a multi-disciplinary team
- Enjoyment in working as part of a cross country QA team
- Excellent attention to detail, experience in RCA and CAPA/PI
- Assist colleagues as and when required
- Demonstrate a 'can do' approach with an open door policy
- Ability to work in a challenging fast paced environment

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.

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