



Position: Quality Assurance Specialist (Part-Time Contractor \leq 20 hours/week)

Reports to: Associate Director, Clinical Quality Assurance

Location: Brisbane, CA

Summary

We are seeking a Quality Assurance Specialist to assist with the administrative support for Aimimmune QA compliance in implementing and enforcing SOPs and cGXP regulations. The position will assist QA management in coordinating Quality based review meetings and providing metrics and other outputs for these meetings, assisting with processing and tracking the related Corrective and Preventive Actions (CAPA) through closure, including updating and maintaining logs and partnering with personnel to meet compliance objectives, deliverables, and timelines.

Specific Responsibilities:

- Organize and host Quality Review meetings
 - Define and publish meeting agendas
 - Work with QS Manager to prepare for and provide metrics and other outputs for scheduled QS review meetings (e.g., monthly or as needed)
 - Draft and finalize QS Review meeting minutes
 - Record and track QS actions/deliverables according to defined due dates in QS logs, trackers, and systems
- Communicate routinely with persons responsible for actions/deliverables to assure progress and on-time completion
- Support QA and investigation team with administrative support for Corrective and Preventive Actions (CAPAs) associated with, e.g.,
 - Product Complaints
 - Deviations
 - Audits/Inspections
 - Vendors
 - Other events
- Performs other duties as assigned by QA management, e.g., Training compliance support
- This position has no supervisory responsibility and works independently with general guidance provided from QA management

Qualifications / Requirements:

- Minimum 3-5 years of relevant work experience in pharmaceutical industry or equivalent (GXP QA preferred)
- Must demonstrate proficiency in English, good verbal and written communication skills
- Proficiency with Microsoft Windows and Office Suite Applications (Excel, Word, Outlook, and PowerPoint)
- Attention to detail and accuracy
- Strong communication, interpersonal, and organization skills
- Ability to read and interpret documents such as policies and procedures
- Capable of following written, and verbal instructions
- Ability to prepare reports
- Project management training and skills a big plus

Preferred Experience, Special Skills, Knowledge:

Expected Aimmune Benefit:

- Improved coordination and closure of QS deliverables to support:
 - inspection readiness
 - increase in number of development projects
 - increase in number of vendors/customers related oversights (e.g., audits, CAPAs)
 - Commercial Vendors
 - Clinical Development Vendors
 - Due Diligence/Customers
- Establishment and maintenance of QS metrics and reports to support
 - Quality Council / Management Review meetings
 - Customer Audits / Regulatory Inspections
 - Quality System effectiveness
- Support QA team objectives
 - eQMS project launch with specific focus on successful launch of QS modules
 - QS task coordination by a QA specialist allows ADs and Directors to work at a more technical level
 - Improved Compliance by constant monitoring of events trackers
 - Improved Communications with global action owners through closure

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.