Position: **Quality Assurance Associate**

Reports to: **Quality Assurance Manager**

Summary

This position's main responsibility is to perform batch record review and liaise with Contract Manufacturing Organizations (CMOs) and/or Contract Testing Labs (CTLs) to close deviations, CAPAs, investigations, and change controls. This QA Associate will participate in and contribute to process improvement initiatives. Improvements include increasing process efficiency, effectiveness and reducing rework and report functionality errors. Additional responsibilities may include supporting internal/external audits and inspection readiness activities.

Specific Responsibilities:

- Review executed production batch records, deviations and investigations
- Partner with Manufacturing, Regulatory Affairs, Clinical Research, Supply Chain, and Quality Control to meet clinical project and product needs
- Represent QA on various projects and support activities associated with manufacturing, testing and release of product
- Support activities related to qualification/validation of equipment and processes
- Revise quality systems procedures as required to maintain a state of compliance with cGMP regulations
- Compile, track quality metrics for critical quality attributes and report to management on a routine basis (i.e., Lot disposition, Deviations, CAPA, Change Control, and Investigations)
- Work with QA Managers to maintain the QA databases for Product Genealogy
- Participate in internal audits
- Contribute and support site Pre-Approval Inspection (PAI) and commercial readiness preparations
- Support training events related to quality procedures, cGMP regulations and guidelines
- Ensures that the quality assurance programs and procedures are adhered to and followed to ensure compliance to cGMP regulations and ICH guidelines
- Perform other QA responsibilities as assigned by management

Qualifications / Requirements:

- A minimum Bachelor's degree in a scientific discipline is required
- 3+ years in the pharmaceutical industry in QA GMP functions in clinical studies (Phase I to III) and commercial operations
- Strong working knowledge of cGMP regulations (for e.g., 21CFR210, 211, 610, 680 and ICH, and ICH guidance's) and Principles of Quality Management (ISO 9000)
- Ability to prioritize and organize work, ensuring attention to detail, and accuracy
- Excellent organizational and time management skills
- Excellent interpersonal, written and verbal communication skills
- Solution focused, sound judgement, positive, self-motivated and has desire to learn new things
- Pro-active in identifying opportunities for improvement along with strong problem solving and negotiation skills
- High degree of customer service, diplomatic, yet assertive with both internal and external customers
- Proficiency with Office software applications, including MS Word, MS Excel, MS Project, MS Power Point
- Training in project management is plus

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 for peanut allergy, AR101, is in Phase 3 clinical testing in North America and Europe. 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.