Position: **Sr. Manager, Quality Validation**

Reports to: **Assoc. Dir. Quality Assurance CMC**

Summary

This position's main responsibility is to provide Quality oversight of facilities, equipment, processes, cleaning, and method validations in a cGMP environment performed for Aimmune at Contract Manufacturing Organizations/Contract Testing Labs. Internal Aimmune validation systems may include computer systems validation oversight. The position will review and approve validation documentation, batch records and change controls, as well as provide input for GMP validation activities against regulatory requirements. Additional responsibilities may include conducting internal/external audits and inspection readiness training. 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 validation activities related to Aimmune products produced at 3rd party CMOs / CTLs.
- Provide Quality oversight and leadership for Computer System validation activities related to Aimmune products at Aimmune.
- Manage and coordinate process monitoring and continuous improvement initiatives as related to validation master plans per GMP requirements, as required.
- Participate in providing quality input for protocol generation, execution, and final package preparation for process, equipment, facility and method validation activities
- Review and approve change controls related to the implementation of process changes, method improvements and equipment upgrades.
- Development and implementation of SOPs/Guideline documents with systemic procedural improvements related to validation activities.
- Manage QA review and approvals of investigations, qualifications, validations protocols and reports.
- 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, validation techniques/approaches and systems utilized at Aimmune.
- Lead and represent QA Validation in multi-departmental meetings & project teams owned by QA Validation.
- Other duties as assigned.

Qualifications / Requirements:

- Bachelor of Arts/Sciences (BA/BS) degree, or higher, in a technical discipline (physical, engineering, chemical or biological sciences) is required.
- 7+ years' experience in a cGMP regulated manufacturing environment, with exhibited knowledge or proficiency in regulations related to process validation, process sciences and change control.
- 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 related to equipment, processes, and regulatory expectations.
- Experience and participation in regulatory inspections presenting departmental functions in audits or regulatory inspections
- Proficiency with standard office software applications, including MS Word, MS Excel, MS Project, MS Power Point.
- Understanding and familiarity with global regulatory requirements, guidelines, and recommendations for cleaning and steaming process validation expectations.
- Proficiency with technical summary report reviews required, with exceptional organizational attention to detail.
- Knowledge of industry standards, guidance documents, and global requirements related to cleaning validation is required.
- Training in project management is a plus.
- Ability to utilize computer to perform tasks.

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.