



Position: Quality Assurance Document Control Specialist

Reports to: Quality Assurance Manager

Location: Brisbane, CA

Summary

The QA Document Control Specialist at Aimmune Therapeutics will oversee and/or assist all facets of document control activities that establish quality systems (QS) compliant with current GxP requirements. The position supports other quality systems resources for the entire product life cycle associated with the development, production and distribution of Aimmune products. The position reports into the QA Manager responsible for Document Control.

Specific Responsibilities:

- Represent QA Document Control, as needed
- Process and finalize Quality System documents and document change requests (DCRs), including making documents effective, superseding, obsoleting, watermarking, stamping, scanning, filing, and notifications to appropriate GxP personnel when new documents require training
- Maintain QA controlled documents file room and update electronic logs for Quality Documents stored in the QA File Room, to keep current and prevent duplications of numbers
- Maintain the Effective SOP List and in parallel maintain the Training Matrix Template
- Prepare training binders for new employees, process paper GxP training records and keep electronic GxP Personnel Training spreadsheet current
- Review, edit, format SOPs and assist with creation of other documents, as needed
- File and maintain manufacturing and supply chain records
- Maintain current list of GxP controlled signatures

Note: Other duties may be assigned, as needed

Qualifications / Requirements:

- A.A.S. in Business Administration or Science field
- A minimum of 5 years of experience in the pharmaceutical industry in Document Control, or Quality Assurance
- Advanced skills in Microsoft Word, Excel and PowerPoint
- Excellent written and verbal communication skills as well as excellent interpersonal skills are a must
- Must have a good understanding of FDA/GMP requirements related to documentation

Preferred Experience, Special Skills, Knowledge:

- Results and goals oriented
- Ability to effectively prioritize with good time management
- Excellent computer skills
- Accuracy and attention to detail
- Organized work habits

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.