Position: **Quality Control Manager, Quality Control**

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

Location: **Brisbane, CA**

Summary

The Quality Control Manager or Senior Scientist, Analytical Development & QC will be a member of the Analytical and QC Team and will support activities associated with quality control and stability testing of Aimmune's drug substances and drug products. Prior experience with quality control release/stability testing of pharmaceutical products, method validations and transfers and the demonstrated ability to work effectively in a virtual quality control testing environment are requirements for the position.

Specific Responsibilities:

- Support the transfer of analytical methods to CTL's for protein based products. These may include HPLC, ELISA and other methods
- Support the preparation of phase-appropriate stability protocols and stability reports for drug substance and drug product in accordance with regulatory requirements and as needed to support clinical trials and regulatory submissions
- Write/contribute to relevant analytical sections for BLA/MAA/IND/IMPD submissions
- Write, review and approve Analytical Development and Quality Control SOPs, specifications, method validation and verification protocols and reports and technical reports
- Write, review and approve method transfer protocols and reports
- Analyze and review quality control release and stability testing data of Aimmune's pharmaceutical products at Contract Testing Laboratories (CTLs) and/or Contract Manufacturing Organizations (CMOs)
- Monitor, trend, and interpret stability data, as necessary, for Aimmune products
- Prepare and review stability tables and trend charts for internal reports and regulatory submissions
- Review and approve out-of-specification (OOS) and out-of-trend (OOT) testing results, deviations
- Work collaboratively with manufacturing/supply chain, quality assurance and project management to ensure timely availability of lot release and stability data and to ensure adequate planning for stability supplies and support regulatory

Qualifications / Requirements:

- B.S. or advanced degree in Chemistry, Biochemistry, Analytical Chemistry, or a related field with at least 10 years relevant experience

Preferred Experience, Special Skills, Knowledge:

- Ability to effectively prioritize and deliver on tight timelines
- Excellent written and verbal communication skills
- Prior experience managing lot release and stability testing at CTL or CMO
- Expertise in use of Excel or comparable software solutions for management of stability data
- Accuracy and attention to detail
- Experience with JMP and/or Minitab
- Excellent cross-functional team participation skills
- Outstanding problem solving abilities.
- Ability to be flexible with changing work needs
- May require travel about 10-20% of time

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.