Position: **Quality Technical Reviewer (Contractor)**

Reports to: **Associate Director, Analytical Development & QC**

Location: **Brisbane, CA**

Summary

In support of drug substance and drug products clinical development, the Technical Quality Data Reviewer will be a contract member of the Analytical Development and Quality Control Team and will support activities associated with quality control and stability testing, as well as, manufacturing development in support of regulatory filing (BLA and MAA for AR101 Peanut Allergy Immuno Therapy). Prior experience with quality control release/stability testing/manufacturing development of pharmaceutical products is required. The individual should have demonstrated ability to work effectively in a virtual analytical development, quality control, and manufacturing environment is also a requirement for the position.

Specific Responsibilities:

- Audit analytical data such as HPLC, ELISA and protein content
- Perform data audits for regulatory filings
- Reconcile audit results from multiple sources and maintain records of completed audits
- Analyze and review quality control release, stability testing, and manufacturing data of Aimmune's pharmaceutical products at Contract Testing Laboratories (CTLs) and/or Contract Manufacturing Organizations (CMOs)
- Prepare and review batch analysis, stability tables, and trend charts for internal reports and regulatory submissions
- Prepare and review manufacturing process development studies for internal reports and regulatory submissions
- Work collaboratively with manufacturing/supply chain, quality assurance, regulatory, and project management to ensure timely availability of lot release, stability data, manufacturing data
- Write and review Analytical Development, Quality Control, Manufacturing control documents: method validation/verification protocols, reports and technical reports, manufacturing process development reports, investigation (OOS/OOT, deviations) reports.
- Additional responsibilities maybe assigned, as required, or in consideration of candidate's expertise and skills

Qualifications / Requirements:

- B.S. or advanced degree in Chemistry, Biochemistry, Analytical Chemistry, or a related field with at least 8-10 years relevant experience in pharmaceutical development in Analytical Development, Quality Control or Manufacturing function
- Prior experience reviewing and analyzing GMP data for analytical methods
- Familiarity with Empower software
- Prior experience in analytics for biopharmaceutical/biologics is preferred
- Experience in the development, validation, transfer, testing with chromatographic (HPLC),

biophysical methods, and immunio methods (ELISA) is required
- Prior experience with contributing to regulatory filing (IND, BLA, NDA or MAA) is a plus

Preferred Experience, Special Skills, Knowledge:

- Ability to effectively prioritize and deliver on tight timelines
- Excellent written and verbal communication skills
- Expertise in use of Excel or comparable software solutions for management of QC, Manufacturing data
- Accuracy and attention to detail
- Time management skills, ability to elevate relevant issues to project lead
- Excellent cross-functional team participation skills
- Demonstrated ability to work as an independent, self-motivated, detail-oriented, result-driven and highly flexible team-player in a fast-paced working environment
- A plus, experience with JMP and/or Minitab or other software for statistical analysis of analytical data

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 recently announced positive top-line data from its pivotal Phase 3 PALISADE trial for AR101, the company's lead investigational drug for peanut allergy. 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.