Position: **Senior Scientist, Analytical Development**

Reports to: **Associate Director, Analytical Development & Quality Control**

Location: **Brisbane, CA**

Summary

The Senior Scientist, AD will be a member of Aimmune's analytical method development team, contributing to early development of pipeline products currently in pre-IND stage. The candidate will support design and development of tests, studies, procedures, and specifications used for control of Aimmune's APIs and drug products. Tests will include cGMP quality control tests and characterization tests to understand important attributes of Aimmunes products: Immunoassays (ELISA), chromatography (HPLC-UV, HPLC-MS), and electrophoresis (PAGE, western blotting). Studies will include ICH studies, product characterization studies, and method characterization / validation studies.

The candidate will be subject matter expert (SME) for development projects, lead planning efforts, and provide detailed interpretation of test results. She/he will oversee QC and stability tests for analytical methods which have been validated and transitioned to QC for regular use. Working closely with Aimmune's regulatory team, she/he will then submit critical studies and documentation to the FDA and international regulatory agencies.

Prior experience with method development of proteins, QC, stability, IND submissions, BLA or NDA submissions, plus the demonstrated ability to work effectively in a virtual environment are important for success in the position. Understanding of applicable USP, ICH, and Ph Eur regulations as they relate to QC testing is highly desirable.

Specific Responsibilities:

- Identify, oversee, and collaborate with contract testing labs (CTLs) and contract manufacturing organizations (CMOs) who analyze food allergens to determine their potency / allergenicity
- Lead the development and validation of analytical methods with CTL's and CMO's for the potency, purity, and content of Aimmune's products. Assays may include HPLC, ELISA, and other methods.
- Use testing information to support manufacturing of oral immunotherapy (allergy desensitization) products. Interpret characterization, product release, and stability data
- Participate in establishment / revision of drug substance and drug product specifications for IND, IMPD, and BLA submissions using statistical analysis and other approaches
- Act as the subject matter expert for investigation and resolution of out-of-specification (OOS) and out-of-trend (OOT) testing results

- Author protocols, reports, and analytical sections of regulatory submissions (IND, IMPD, BLA)

Qualifications / Requirements:

- Advanced degree (Ph.D. or MS) in Chemistry, Biochemistry, Analytical Chemistry, or a related field with at least 4 years relevant experience in a pharmaceutical cGMP environment, or BS with at least 7 years of experience

Preferred Experience, Special Skills, Knowledge:

- Strong working knowledge of protein chemistry and analytical test methodologies: Immunoassays, chromatography, and electrophoresis. Understanding of the biology of antigen-antibody interactions is a plus
- Excellent written and verbal communication skills. Technical writing for IND and regulatory submissions is desirable
- Expertise in use of Excel or comparable software solutions for management and analysis of data. Experience with JMP and/or Minitab is desirable
- Accuracy and attention to detail
- Excellent cross-functional team participation skills
- Outstanding problem solving abilities
- Ability to work independently and effectively
- Ability to prioritize and deliver on tight timelines

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.