Position: **Senior Development Engineer, Early Development**

Reports to: **Manager, Sourcing and New Product Development**

Location: **Brisbane, CA**

Summary

Aimmune is recruiting for a talented and motivated individual to support formulation and process development activities for pipeline drug products for the treatment of food allergies. The successful candidate will develop novel manufacturing processes at contract manufacturing organizations, develop product specifications, interface with raw material suppliers, and prepare CMC information for health authority submissions (IND/IMPD). Candidates should have a pharmaceutical development and/or manufacturing background, preferably with solid oral dosage forms, and a demonstrated ability to thrive in a fast-paced environment requiring delivery on multiple projects. Prior experience in supporting clinical drug product manufacturing and the demonstrated ability to work effectively in a virtual contract manufacturing environment are desirable.

Specific Responsibilities:

- Design experimental protocols to optimize drug product formulations and manufacturing processes using sound scientific methodologies (e.g., DOE)
- Identify and evaluate feasibility of novel manufacturing processes to meet unique product requirements for allergenic source materials
- Communicate with contract manufacturing organizations to plan and execute development activities, stability studies, and product testing
- Travel to contract manufacturing organization sites, as needed, to provide technical guidance and ensure effective collaboration
- Support cGMP clinical manufacturing and packaging of drug products, including planning, batch record approval, investigations, and material logistics
- Interface with key raw material suppliers
- Provide CMC subject matter expertise for health authority submissions (IND/IMPD)

Qualifications / Requirements:

- A minimum of a BS in engineering or life sciences with at least 5 years of experience in pharmaceutical development and/or manufacturing (an equivalent combination of education and experience may be considered)
- Good working knowledge of cGMP requirements, including FDA, EU, and ICH guidelines as they relate to clinical product development
- Ability to travel up to 20% of the time

Preferred Experience, Special Skills, Knowledge:

- Effective collaboration with contract manufacturers and/or external laboratories
- Prior experience with solid oral dosage formulation development is desirable
- An understanding of protein chemistry and testing techniques is desirable
- Ability to apply statistical analysis approaches to CMC development data
- Outstanding creative problem-solving abilities, technical writing skills, cross-functional team participation and communication, accuracy, and attention to detail
- Ability to work independently and effectively 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.