Position: **Associate Director, Statistical Programming**

Reports to: **Director, Statistical Programming**

Location: **Brisbane, CA**

Specific Responsibilities:

- Lead statistical programming activities related to regulatory submissions for multiple studies
- Develop programming tools that improve efficiency and quality
- Set up programming processes supporting global submission
- Identify and write SOPs
- Partner with vendors on all programming deliverables for global submission
- Collaborate with data management, clinical development, and medical affairs to identify programming needs and manage the workflow
- Manage programming timelines and ensure appropriate resource allocation for the assigned projects
- For assigned projects, provide programming activities oversight, including in house validation of vendor output and ISS and ISE activities
- Work with manager and HR to evaluate resource needs and recruit programming team members
- Manage internal programming team including staff development and career growth

Qualifications / Requirements:

- BS + 14 Years, MS + 10 Years, PhD + 8 years, preferably in Mathematics, statistics, computer sciences or other related fields
- At least 4 years of people management experience required
- Experience in developing dataset (SDTM/ADaM) and TFL specification for programmers to use
- Led statistical programming activities including eCTD for at least one FDA/EMA submission
- Expertise in CDISC activities and regulatory submission preparation
- Experience in managing external vendors including programming and validation plans for deliverables including QC of outputs

Preferred Experience, Special Skills, Knowledge:

- Thorough knowledge of the drug development and regulatory submission cycle
- Excellent project management skills
- Excellent communication skills

- Able to work in a fast pace and agile environment
- In-depth and current knowledge of regulatory requirements and guidance
- Excellent SAS and CDISC skills
- Proficiency in MS Word, Excel, PowerPoint, and Project

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 for peanut allergy, AR101, is in Phase 3 clinical testing in North America and Europe. 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.