



Position: Director, Biostatistics
Reports to: Vice President, Biometrics
Location: Brisbane, CA

Summary

The Director will serve as the statistical lead of Aimmune studies and will report to the VP of Biometrics. This is a leadership position with a large hands-on component.

Specific Responsibilities:

- Lead the biostatistics function to develop and execute statistical strategy in design and analysis of clinical trials across programs
- Provide biostatistics leadership to cross-functions, i.e. clinical science, project management, medical affairs, pharmacovigilance, and clinical operations
- Author statistical analysis plans for individual studies, ISS and ISE
- Provide input into CDISC standards across studies and programs
- Collaborate on project development plans, regulatory, scientific and commercial projects
- Manage external statistical vendors
- Manage internal staff
- Develop SOPs and ensure compliance with process & quality of deliverables within the development program.
- Communicate statistical analysis results in data presentations and scientific reports, including clinical trial, exploratory and meta-analysis results
- Support publication activities and scientific presentations
- Maintain expertise in the field of biostatistics, and bring best practices and new methodologies in house
- Author or contribute to reports and/or scientific presentations and manuscripts

Qualifications / Requirements:

- Ph.D. or M.S. in statistics, biostatistics, or related field with minimum 10 years of experience as a biostatistician in the biotech/pharmaceutical industry
- Management experience with leading biometric groups
- Extensive knowledge of GCP, ICH guidelines, FDA regulations, CDISC standards/implementation guides, 21 CFR Part 11, and familiarity with EMA/CHMP regulations and guidelines, and other international regulatory requirements
- In-depth knowledge of the global drug development process
- Experience with regulatory submissions required

- Excellent verbal and written communication skills
- Excellent interpersonal and project management skills

Preferred Experience, Special Skills, Knowledge:

- Experience in the allergy and immunology fields preferred

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.