Senior Director, Analytical Development & Quality Control

The Senior Director, Analytical Development & Quality Control will be the functional lead and have primary responsibility for all activities associated with analytical method development/optimization, quality control, and stability testing of Aimmune's APIs and drug products. The successful candidate will work closely with Manufacturing/Supply Chain, Quality Assurance, Project Management, and Regulatory Affairs to ensure timely development and validation of methods as well as the timely testing and release of materials. This person will be responsible for the collection of data and the finalization of the reports and summaries required to support global regulatory submissions. In addition, this person will be responsible for establishing and maintaining excellent working relationships with multiple contract testing laboratories. Prior experience with method development/validation and the demonstrated ability to work effectively in an environment that utilizes contract testing laboratories for analytical development and quality control testing are requirements for this position.

Responsibilities include:

- Manage and develop members of the Analytical Development (AD) & Quality Control (QC) team at Aimmune
- Advance and maintain Aimmune's systems for quality control and stability testing of pharmaceutical starting materials, intermediates, and final products
- Advance and manage Aimmune's internal product specification system
- Oversee all activities associated with quality control and stability testing of Aimmune's pharmaceutical products at Contract Testing Laboratories (CTLs) and Contract Manufacturing Organizations (CMOs)
- Identify and address technical and validation gaps in analytical methods and QC testing in preparation for BLA/MAA submissions and product commercialization. Work with CTLs and CMOs to devise and implement improvements in analytical methods
- Identify, evaluate, and implement new analytical methods and quality control strategies for early-stage products
- Ensure compliance of Aimmune analytical testing activities with applicable compendia (e.g., USP, NF, EP) and regulatory guidance documents
- Coordinate and oversee analytical methods transfers to and between CMOs and CTLs
- Manage the development and supplies of reference standards and critical reagents across testing sites
- Contribute to or oversee the investigation and resolution of out-of-specification (OOS) and out-of-trend (OOT) testing results
- Work collaboratively with Manufacturing/Supply Chain, to ensure that QC analytical methods are aligned with process needs/capabilities and product requirements
- Serve as primary author or reviewer of CMC sections related to analytical methods and method validation, specifications, and stability in INDs, IMPDs, NDAs, BLAs, and other regulatory submissions

Qualifications include:

- Advanced degree in Chemistry, Biochemistry, Analytical Chemistry, or a related field preferred
- At least 15 years relevant experience including at least 10 years in a combination of QC and AD. Previous managerial experience required.
- Direct applied experience with analytical method development and validation
- Demonstrated experience with ELISA-based methods and protein analysis required.
- Comprehensive working knowledge of Good Manufacturing Practices (cGMPs) and Regulatory Guidance Documents as they relate to development, testing and stability of pharmaceutical products
- Ability to travel up to 20% of the time
- Ability to effectively prioritize and deliver high-quality results on tight timelines
- Self-starter with demonstrated ability to deliver high-quality results in a fast-paced development environment
- Excellent written and verbal communication skills
- Accuracy and attention to detail
- Excellent cross-functional team participation skills
- Outstanding problem-solving skills including the ability to devise and implement practical solutions to resolve complex issues in a virtual environment
- Ability to recognize the potential of new technologies to meet Aimmune product testing requirements

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.