



Position: Senior Scientist, Biologics Analytical Development

Reports to: Associate Director, Analytical Development & QC

Location: Brisbane, CA

Summary

The Senior Scientist, AD will support Aimmune's project goals by leading biologics analytical development activities, including method development, qualification, validation, and product characterization in support of Aimmune's preclinical and clinical therapeutics.

Specific Responsibilities:

- Lead biologics analytical development activities (methods, testing) for project(s) including drug substances such as peptides, proteins, vaccines, and allergen extracts
- Independently lead the development, qualification, and validation of analytical methods for purity, content, and other product attributes supporting rapid formulation development, product release and stability testing at CROs / CMOs. Methods will include ELISA, SRID, and ligand binding assays and may include chromatography assays, and peptide mapping assays with mass spectrometry detection
- Author and complete test method procedures, qualification reports, and other reports, as required. Write controlled documents (test methods, protocols, reports) for analytical test methods and for API characterization
- Independently conduct characterization of drug substances and products using biophysical, spectroscopic, and other analytical techniques.
- Coordinate project activities with other departments (e.g. formulation, manufacturing, engineering)
- Present progress on projects to project teams and management.
- Perform all work in accordance with company policies, consistent with regulations and guidance for GMP products

Note: Essential Duties and Responsibilities include the previous. Other duties may be assigned.

Qualifications / Requirements:

- BS in **Analytical Chemistry**, **Chemistry**, Biochemistry, or Pharmaceutical science with a minimum of +12 years, MS with +7 years' experience in the pharmaceutical or biopharmaceutical industries, or a PhD in with minimum +3 years' experience in the pharmaceutical or biopharmaceutical industries

- Thorough understanding of regulatory agency (FDA) requirement and international guidance (ICH) for drug substance and product under GMP is required
- Chromatography skills:
 - A minimum of 3 years hands-on experience developing, qualifying, and validating chromatographic methods (HPLC, GC), spectroscopic methods, and other physical and biochemical methods to analyze biologic or protein drug substances and drug products is required.
 - Demonstrated experience with development of peptide mapping or mass spectrometry assays is a plus
- Immunoassay skills:
 - Demonstrated experience with development, qualification, and validation of ELISA or other immunoassays for potency, identity, and purity analysis for drug substance or product release is required.
 - Single Radial Immunodiffusion (SRID) experience for analysis of vaccine products is a plus
 - Experience with surface plasmon resonance (Biacore) or DLI (Octet) system for quantitative and qualitative assays is a plus
- Data analysis skills
 - Proficiency in Excel is required
 - Proficiency with JMP or MiniTab is a plus
 - Trend analysis, control charts, statistical process control, and six sigma are a plus
- General skills:
 - Demonstrated ability to multi-task in high activity environment is required
 - Excellent written and verbal communication skills are required
 - Experience in managing junior staff is a plus

ORGANIZATIONAL RELATIONSHIPS:

- Interacts with project management and team personnel

EXTERNAL RELATIONSHIPS:

- Interacts with suppliers and consultants

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.