Position: Manager / Sr. Manager, Clinical Manufacturing

Reports to: Sr. Director, Manufacturing and Process Development

Aimmune is recruiting for a talented and motivated individual to support clinical stage drug product manufacture and packaging activities at contract manufacturing sites. The activities include, but are not limited to, support of day-to-day manufacturing operations at CMOs, product and process change management, and equipment (manufacturing, packaging and testing) upgrade and re-qualification. The incumbent will contribute to Aimmune's overall success in the development of treatments for food allergies by providing critical technical support to clinical manufacturing and implementing process improvements. The ideal candidate will have a biopharmaceutical development/manufacturing background, preferably with solid oral dosage form experience, and an ability to thrive in a fast-paced environment requiring delivery on multiple projects on tight timelines. The successful candidate will work closely with Contract Manufacturing Organizations, Contract Packagers, Clinical Supply Chain, Regulatory, Quality Assurance, and CMC Project Management to ensure timely delivery of Aimmune clinical trial materials. Prior experience in supporting clinical drug product manufacturing and the demonstrated ability to work effectively in a virtual contract manufacturing environment are requirements for this position.

ESSENTIAL DUTIES

- Supports clinical manufacture of drug products including primary and secondary packaging (e.g., batch record review, investigations, specifications, sampling and in-process control)
- Contributes to the definition of the drug product including CTQ attributes and facilitates evolution of the manufacturing process through the phases of clinical development
- Leads change management efforts relating to process and capacity improvement of drug product manufacture in collaboration with regulatory and QA
- Guides process and test equipment qualification and re-qualification effort
- Designs protocols to find operating ranges for drug product manufacturing processes using scientific methodologies (e.g., DOE). Performs risk-based assessments to identify key process parameters affecting CTQ attributes
- Assists with review and implementation of other quality system and plant maintenance (e.g., EM) procedures in support of drug product manufacturing per cGMP guidelines
- Provides subject matter expertise for regulatory inspections and filings
- Assists other team members with new product development efforts and other activities, as needed

QUALIFICATIONS/REQUIREMENTS

Education and/or experience:

- BS or MS in engineering, sciences or relevant discipline. Candidates at the Manager will typically have 5+ years of biopharmaceutical experience in a manufacturing environment; Sr. Manager candidates will typically have 8+ years of experience
- Comprehensive working knowledge of cGMP requirements and FDA, USP and ICH guidelines as they relate to clinical manufacture, process development and manufacturing process validation for final dosage forms and primary/secondary packaging operations
- Demonstrated experience with oversight of day-to-day drug product manufacturing and packaging operations
- Direct experience with design and optimization of processes for producing clinical supplies
- Experience working with CMOs in a virtual environment
- Ability to travel up to 30% of the time

Special skills/knowledge:

- Detail-oriented with good organizational and project management skills
- Self-starter with demonstrated ability to deliver high-quality results in a fast-paced development environment with minimal supervision
- Solid proficiency in technical writing (e.g., protocols, reports, SOPs) and effective verbal communication skills
- Excellent cross-functional team participation skills
- Adept in computer skills with expertise in MS office programs and statistical analysis tools

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.