**Position:** **Manager / Sr. Manager, Packaging Engineering and Labeling**

**Reports to:** **Sr. Director, Manufacturing and Process Development**

**Location:** **Brisbane, CA**

**Summary**

Aimmune is recruiting for a talented and motivated individual to guide and manage packaging and labeling activities at their contract manufacturing sites. The incumbent will contribute to the overall success of the food allergy manufacturing business, providing oversight for all drug product packaging activities including drug product track and trace systems. The position works with contract packagers and third party vendors to design and develop primary and secondary packaging and labeling in compliance with all regulatory requirements. The ideal candidate will have biopharmaceutical experience with an ability to thrive in a fast-paced environment and deliver on multiple projects on tight timelines. The successful candidate will work closely with outside contract packagers, clinical and commercial Supply Chain, Quality Assurance, Manufacturing and Sales/Marketing to develop and deliver packaging strategies in preparation for commercial readiness and launch. Prior experience in pharmaceutical product packaging engineering, labeling, and the demonstrated ability to work effectively in a virtual contract packaging environment are requirements for this position.

**Specific Responsibilities:**

- Support successful commercial launch of Aimmune's products by providing packaging vendor selection, oversight, label artwork development, validation strategy, and product track and trace solutions
- Bring and develop packaging expertise into the organization and function as a key communication interface between Aimmune's Sales/Marketing, Manufacturing, Quality, Regulatory, external suppliers, and consultants in the development and execution of packaging strategies
- Develop serialization solutions in collaboration with Quality Assurance, Finance, Information Technology, and marketing and packaging vendors in order to meet global requirements for product traceability
- Interface with internal and external stakeholders to implement and validate product track and trace solutions
- Oversee validation work at contract packagers as related to packaging and integration of new processes or equipment
- Troubleshoot packaging problems, document findings and implement solutions to resolve problems.
- Coordinate with commercial Supply Chain, Manufacturing, Regulatory, and QA to ensure timely release and shipment of packaged product to Commercial Distributors
- Assist the supply chain team with sourcing of 3PLs and other contract-based service providers
- Assist Clinical Supply Chain and Early Development groups to develop packaging options that best meet the needs of the clinical trial design while satisfying product requirements
- Author packaging related sections of regulatory submissions
- Conduct investigations of out-of-specification (OOS) and out-of-trend (OOT) testing results related to packaging and recommend [implement] appropriate CAPAs

- Prepare and deliver development reports, protocols, batch records, and SOPs supporting packaging development and regulatory submissions
- Oversee packaging activities at packaging sites as Person in Plant, as needed

**Qualifications / Requirements:**

- BS or MS in engineering or life sciences, with 8+ years of biopharmaceutical experience in a packaging, engineering, and validations environment
- Comprehensive working knowledge of cGMP requirements per FDA, USP and ICH guidelines
- Familiarity with and experience in applying global regulatory requirements for packaging and labeling of commercial pharmaceutical products
- Understanding of DSCSA regulations specific to drug product serialization and computer system validation guidelines (21CFR Part 11, GAMP5) is preferred
- Exceptional verbal and written communication skills (e.g., protocols, SOPs), and strong negotiation skills
- Travel up to 15% of the time

**Preferred Experience, Special Skills, Knowledge:**

- Detail-oriented with good organizational and project management skills
- Self-starter with demonstrated ability to discern project requirements and develop an effective approach to deliver high-quality results in a fast-paced development environment
- Expertise in computer skills: Microsoft Word/Excel/PowerPoint, Project/Visio
- Working knowledge of ERP systems and drug product track trace systems is highly desirable but not required
- Outstanding problem solving skills including the ability to devise and implement practical solutions to resolve complex issues in a virtual environment
- Flexibility and the ability to manage changing needs

**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.