Position: **contract Biospecimen Operations Specialist**

Reports to: **Director, Clinical Operations**

Summary

Supporting the portfolio, the Biospecimen Operations Specialist is responsible for developing the process to manage and track clinical specimens in accordance with informed consent requirements with the highest degree of quality.

Responsibilities include:

- Accountable for planning, organizing and overseeing the collection and shipping of samples from Central Labs to collaborators for analyses
- Develop specimen management plans to ensure complete accountability, traceability and overall management of specimens from clinical studies including reconciling against informed consent
- Develop the strategy for a scalable sample storage, tracking and access
- Manage relationships with laboratory vendors, including forecasting and tracking of study costs associated with sample management
- Establish, implement, and maintain processes for sample management for consistency across programs
- May develop study-specific sample management plans to document cross-functional agreements on the lifecycle and reconciliation plan for each sample type
- May support sample analysis data transfer, data reconciliation, and data review
- Maintain professional knowledge of current GCP, biobanking, and sample management policies and best practices and ethical guidelines and apply knowledge appropriately

Qualifications include:

- Bachelor's degree in a scientific discipline and a minimum of 2 years of related experience.
- Demonstrated understanding of pharmaceutical regulatory requirements, both US and abroad
- Demonstrated knowledge of ICH and GCP
- Effective team player and ability to collaborate with cross functional clinical study teams
- Ability to manage lab vendors and oversee sample management activities across multiple clinical trials
- Demonstrated ability to work independently to manage complex projects with multiple priorities in a fast paced, team-based environment
- Excellent written and communication skills necessary to interface with vendors and team members
- Direct experience in managing sample operations of various sample types
- Experience with vendor and CRO management

- Proficient with sample data reporting, managing metrics and understanding the overall quality and stability of study samples

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.