



Position: Director, GxP Applications

Reports to: Senior Director, IT and Corporate Services

Summary

Reporting to the Senior Director, IT and Corporate Services, the Dir GxP Applications will partner with business leaders to align IT efforts with business requirements. Engage client leadership and IT to ensure that technology architecture, and governance are aligned to strategic business initiatives.

Specific Responsibilities:

- Provide strong understanding of business core functions needs considering short and long-term strategy
- Provides guidance and counsel on technology available that drives delivery of solutions consistent with business direction
- Manage technology investments to align with IT architecture and roadmap in partnership with the business
- Collaborate with Legal and Compliance departments in development and implementation of compliance initiatives
- Lead / manage internal and external resources in support of business-related projects and activities
- Collect and analyze business requirements, design and document work flow of data between systems to enable the application selection/development
- Develop functional specifications to support systems and business process design that align with the IT Strategic plan
- Collaborate with business functions and technical team through the development and testing of solutions such as screen, interface and GUI designs; ensure all approved requirements are met
- Facilitate the evaluation and selection of new applications and functions and determine issues in services and software
- Represent IT during FDA inspections and audits

Qualifications / Requirements:

- Bachelor's degree in Business, Computer Science or Information Systems
- Master's in Business is a plus
- 10+ years of experience in IT building and supporting enterprise applications
- Strong business knowledge and ability to operate as the IT applications SME
- Knowledge and experience working within an SDLC framework
- Public company experience including working in a regulated SOX environment

- Prior experience working in the Life Science industry including pharmaceutical, biotechnology or medical device required
- Ability to analyze and define business requirements and translate into technical solutions
- Effective project management skills are essential; change management capability and desire to innovate and help lead change
- Excellent organizational, interpersonal and customer service skills; excellent communicator with active-listening skills
- Proven adaptability to shifting project schedules, priorities and assignments; able to make effective decisions under pressure
- Demonstrated problem-solver in a dynamic, fast-growing team environment
- Experience with the following system types/platforms preferred: CTMS, eTMF, SAS, Data warehouse, BI, Safety, QMS, and EDMS

Preferred Experience, Special Skills, Knowledge:

- Strong written and oral communication skills
- Strong presentation and interpersonal skills
- Exceptional analytical, conceptual and problem-solving abilities
- Able to prioritize and execute tasks in a high-pressure environment
- Exercise judgment within broadly defined practices and policies in selecting methods, techniques and evaluation criteria for obtaining results
- Excellent organizational skills and the ability to balance several on-going projects simultaneously
- Ability to communicate ideas in both technical and user-friendly language
- Experience working in a team-oriented, collaborative environment
- Working knowledge with CFR 21 Part 11, GxP Validated Systems, and Sarbanes-Oxley Regulations

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.