Position: **Vice President, Drug Safety & Pharmacovigilance**

Reports to: **Chief Medical Officer**

Summary

Reporting to the CMO, the Vice President, Drug Safety & Pharmacovigilance will lead in the strategic management and global oversight of our Drug Safety & Pharmacovigilance systems, ensuring corporate compliance with all applicable US and foreign legal and regulatory requirements. Will ensure medicinal product benefit-risk evaluations and appropriate communications to stakeholders (e.g. Regulators, Institutional Review Boards/Ethics Committees, Investigators, Internal).

Responsibilities include:

- Drug Safety Strategy including policies, systems and processes to support corporate goals, which include completion of Clinical Trials and filing of BLA and MAA
- Drug Safety Governance to ensure fulfilment of all applicable US and foreign legal and regulatory requirements
- Executive Sponsor of Safety Database, Registry Database, Adjudication System
- Ensure proper management of Aimmune's internal Safety Monitoring Committee, Data Monitoring Committee(s) and Adjudication Committee(s)
- Provide ongoing updates on the changing risk-benefit profile of Aimmune's drug product(s) in clinical trials and implement appropriate safety updates and risk mitigation plans
- Work collaboratively cross functionally to ensure accurate medicinal product benefit-risk assessments including ISS/ISE, establish effective signal management practices and accurate Reference Safety Information and Safety Communications (e.g. Dear Doctor Letter)
- Oversee and provide functional area approval of Clinical Study Reports, Development Safety Update Reports, Risk Management Plans and Clinical Trial Protocols
- Ensure appropriate safety oversight of post-approval studies
- Review and approve drug safety information from clinical sources in accordance with WHO-ICH guidelines and the appropriate regulatory agencies, including FDA
- Provide oversight of all clinical safety activities including review of medical coding of AEs, con-meds, and processing of SAEs through the entire lifecycle including preparation of analyses or similar events (ASE) for unexpected and related serious adverse events (SUSARs) from clinical trials
- Respond to and resolve safety questions from regulatory authorities, as well as regulatory agency audits and inspections, and corrective action plans
- Directs the development, preparation and compliance of periodic an annual safety reports (e.g., DSUR, PSUR, periodic line listings, BLA safety updates, etc.) investigator communications, product labeling/package inserts and other reports as necessary
- Provides medical expert safety review input into all critical documents for clinical development of products (e.g., protocols and amendments, ICFs, IBs, IMPDs, clinical research reports, INDs, CTAs)

- Manage internal team and external contractors to ensure delivery of quality safety and pharmacovigilance services, including selecting, developing, training, and evaluating team to ensure the efficient operation of the drug safety function
- Develop and implement SOPs and other controlled documents to support investigational and marketed product safety surveillance
- Support audits/inspections of systems and procedures to ensure quality, integrity and compliance with pharmacovigilance and safety reporting regulations, including authoring of responses to regulatory findings relevant to safety operations and processes
- Contribute to safety analyses in Regulatory submissions (e.g. MAAs, BLAs), publications and presentations
- Maintain clinical and technical expertise in the therapeutic areas in which Aimmune operates (i.e., through review of scientific journals, attend scientific and key technical meetings etc.)

Qualifications / Requirements:

- Medical degree with 15+ years of experience in the pharmaceutical or biotechnology industry combined with 10+ years in leadership positions in drug safety and pharmacovigilance
- Thorough understanding of the cross functional drug development processes (Clinical Operations, Data Management, Biostatistics, and Regulatory affairs) and context applicable to safety surveillance activities
- Strong working knowledge of global PV requirements (e.g. ICH E6, ICH E2A, ICH E2B, ICH E2F, US Code of Federal (CFR) regulations; European Union (EU) Regulations and Directives)
- Knowledge of MedDRA terminology and its application.
- Experience in the preparation and authoring of Aggregate Reports (e.g. DSUR, PBRER), RMP, and RSI
- Proficiency with standard desktop computing programs (e-mail, Word, Excel) and relational databases
- Excellent verbal and written communication skills, detail-oriented personality, and ability to work across functions
- Previous experience with CTA filing and maintenance and BLA/MAA submission support required
- Experience in managing CRO or vendors
- Must be highly collaborative, committed to effective team work, self-motivated, well organized, detail-oriented and able to multi-task with delivering high quality work; must be able to develop business solutions to complex problems
- Must be a highly skill manager with a focus on professional development of direct reports
- Demonstrated leadership skills and ability to influence across external functions and within internal team
- Must have excellent, concise writing skills, excellent communication and interpersonal skills, and experience in working in multidisciplinary teams; actively drives strong teamwork and collaboration with an enterprise-wide perspective
- Previous experience with CTA filing and maintenance and BLA/MAA submission support required. Must be able to manage own work, with ability to prioritize, plan and organize work assignments while working under strict timelines
- Must be able to develop business solutions to complex problem
- High degree of Emotional Intelligence, with excellent interpersonal, self-leadership and influencing skills
- Committed to the values of integrity, accountability, transparency, scientific rigor and drive
- Current US work authorization required
- Ability to travel domestically and internationally

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.