Position: **Senior Manager, Drug Safety & Pharmacovigilance (3, Clinical Science)**

Reports to: **Director, Drug Safety**

Location: **London, UK**

Summary

Reporting to the Director Drug Safety & PV (DSPV), the Senior Manager DSPV will assist in the strategic management and global oversight of our DSPV systems, contributing to corporate compliance with all applicable US and foreign legal and regulatory requirements.

Specific Responsibilities:

- Implementation and maintenance of policies, systems and processes to support corporate goals, which include completion of Clinical Trials and filing of BLA and MAA
- Management of Master Files (e.g. TMF, PSMF)
- Assist in management of Aimmune's internal Safety Monitoring Committee, Data Monitoring Committee(s) and Adjudication Committee(s)
- Manage safety analyses and signal detection activities and contribute to the Reference Safety Information and Safety Communications (e.g. Dear Doctor Letter)
- Contribute to Clinical Study Reports, Development Safety Update Reports, Risk Management Plans and Clinical Trial Protocols
- Manage case processing vendor and ensure timely ICSR submissions for Clinical Trial and marketed medicinal products (e.g. SUSAR)
- Manage 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
- Assist 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
- Maintain 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:

- Life science degree with 5+ years of experience in drug safety and pharmacovigilance
- Understanding of the cross functional drug development processes (Clinical Operations, Data Management, Biostatistics, and Regulatory affairs) and context applicable to safety surveillance activities

- 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
- 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 preferable
- 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 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
- Must be able to manage own work, with ability to prioritize, plan and organize work assignments while working under strict timelines
- Committed to the values of integrity, accountability, transparency, scientific rigor and drive
- Current UK work authorization required
- Ability to travel domestically and internationally

Preferred Experience, Special Skills, Knowledge:

- Professional attitude
- Self-sufficient approach to work
- Problem solving

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, AR101 for peanut allergy, is in Phase 3 clinical testing in North America and Europe. The company also plans to begin clinical testing of its investigational drugs for egg allergy and walnut allergy. Headquartered in Brisbane, California – the heart of San Francisco's biotechnology hub – 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.