Position: **Associate CRA Manager (Clinical Operations) - Consultant**

Reports to: **EU CRA Manager**

Location: **Remote (field based)**

Summary:

Provides support to EU CRA Manager on oversight and management of CRA activities.

Specific Responsibilities:

- Involvement in interview and selection of regional contract CRAs and headcount CRAs for Aimmune clinical trials
- Induction and training of new CRAs and mentoring / coaching of CRAs, as needed
- Maintain oversight of CRA activities including training, performance evaluations and CRA transition plans
- Conduct co-monitoring activities to provide oversight of internal and external CRA performance
- Perform study visits (feasibility, PSSV, SIV, IMV, Close-Out) if required, to act as back-up for CRAs
- Assist in audit preparation activities
- Assist with the creation of project specific documents and tools e.g., Monitoring Guidelines and Conventions, Meeting materials/ manuals, tracking spreadsheets/databases, training tools/materials, etc.
- Maintain timely and effective communication among CRAs and study team
- Keeps CPM and management apprised of CRA or study issues, seek guidance as appropriate
- Works with CRA manager and CPM team to determine study requirements, resource and capabilities
- Support CPMs and CRA Manager, as required, in relationship management tasks (e.g. tracking study metrics, sample management, supplies, etc.) and evaluating CRA performance
- Responsible for first-line approval of vendor expenses
- May review CRA monitoring visit reports
- Presents at CRA meetings
- Attends clinical operations team meetings
- Attends/leads CRA team meetings
- Follows ICH-GCP and FDA regulations and contributes to GCP inspection readiness activities
- Other duties and assignments as required for the overall success of studies. Duties may change based on business need and the status of clinical programs

Qualifications / Requirements:

- BS/BA, RN, or equivalent with **at least 2 years' experience in a lead CRA role and 7 years' clinical trial monitoring / clinical trial management experience i**n accordance with CFR, GCP and ICH Guidelines, proficiency with Microsoft Office (Excel, Word, PPT, etc.)

Preferred Experience, Special Skills, Knowledge:

- Full time home-based position

- Previous CRA management experience preferred
- Excellent verbal and written communication skills
- Excellent organizational, record retention, time management, decision making, customer service, and interpersonal skills
- Good command of written and spoken English language
- Ability to travel domestically / internationally (up to 50%)

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.