Position: Manager, Clinical Supply Chain Operations UK

Reports to: Director, Clinical Supply Chain Operations-US with dotted line to Clinical Operations-UK

The Manager Clinical Supply Chain Operations-UK will work as an integral member of the Aimmune team, aiding in the development of investigational drug products used in Oral Immunotherapy (OIT) treatments across global functional teams. The successful candidate will with minimal guidance, proficiently manage the clinical supply chain activities for investigational medicinal products (IMP) and clinical trial materials (CTM) used in Aimmune clinical and non-clinical studies across UK and EU regions.

The core responsibilities include a high aptitude for managing complex clinical supply chain storage and distribution for Aimmune studies, management of vendors performing the packaging, labeling, distribution, inventory, returns, and destruction of IMP/CTM. The position closely interacts with Aimmune's Clinical Supplies, Clinical Development/ Operations, Manufacturing, Quality Assurance, and Regulatory groups, and with external vendors. Prior experience with managing the supply chain for IMP/CTM to clinical sites in the UK and EU, and other regions as demonstrated ability to work effectively and independently in a virtual manufacturing environment are requirements for the position.

ESSENTIAL DUTIES:

- Proficiently manage and coordinate all aspect of Aimmune clinical and/or collaborative studies and projects assigned as UK/EU Study Lead to ensure continuity of clinical and non-clinical supplies by managing distribution activities, troubleshoot depot to depot and depot to site shipments, continuously monitoring inventories with demand and manufacturing forecasts, Interface with internal and external contacts as required.
- Skillfully develop and maintain IRT/IXRS systems by working with US Clinical Supplies colleagues, Clinical Operations and outside vendors to design, test and implement the IRT/IXRS system used to automate the distribution of IMP/CTM to drug depots and clinical sites.
- Be the QP/Clinical Supply Chain liaison/schedule manager and point person for Aimmune QA regarding EU/UK studies working with internal RA group and vendor QPs.
- Efficiently manage labeling (in multiple languages, and over labeling), packaging, inventory, distribution, and final reconciliation of IMP/CTM for multi-national clinical studies.
- In conjunction with Clinical Operations and Quality Assurance, develop requirements and training documents for clinical study drug and other drug supply projects as required (GLP, non-GLP non-clinical), including label copy, packaged product specifications, manuals and training presentations, product shipping and storage specifications.

- Produce/coordinate documentation generation and ensure successful UK/EU within regions and export to US to maintain and ensure compliance with all applicable CTM material import / export regulations.
- Develop new functional SOPs, as necessary, and provide training on CTM to Aimmune staff.
- Manage and oversee study related ancillaries such as but not limited to food challenge materials.
- Develop and maintain applicable metrics to monitor performance relative to clinical trial inventory and planning.
- Provide general Clinical Supply and CMC support to projects and products, as needed.

QUALIFICATIONS/REQUIREMENTS

Education and/or experience:

- Bachelor's Degree in applicable discipline and a minimum of 3 to 5 years professional experience, or equivalent experience, in pharmaceutical/biotech industry and two years minimum experience with IMP/CTM supply management.
- Experience in managing complex products and distribution of IMP/CTM supply chains for double-blinded, placebo-controlled clinical trials in multiple geographies .
- Understanding of Annex 13, 15, 16 as well as ICH guidelines, global label development regulations and guidelines governing conduct of clinical studies a must with experience in cold chain logistics.
- Demonstrated proficient knowledge of international regulations governing transport and distribution of CTM materials.
- Flexibility to travel on company business as required.

Special skills/knowledge:

- Strong interpersonal skills and ability to function in a dynamic cross-global-functional team environment.
- Accuracy and attention to detail is a must.
- Adaptability, agility, flexibility, independence, and resourcefulness to multi-task as needed to thrive in a dynamic small company environment.
- Strong computer skills, with proficiency in spreadsheet, presentation, clinical eSystems, word processing software.
- Excellent written and verbal communication skills.
- Skillful and resourceful with IMP labeling requirements and QP release process. Annex 13, 15 & 16 as well as 21CFR a must and ability to adjust to Brexit implications.
- MBA, CSCP/CPM Certification or similar is a plus.
- Experience with GMP manufacture of drug products for clinical use is a plus.
- Broad exposure to multiple dosage forms and extensive SKUs is a plus.

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.