Position: Manager Clinical Supply Chain Operations

Reports to: Director, Clinical Supply Chain Operations

The Manager Clinical Supply Chain Operations will work as an integral member of the Aimmune team, assisting in the development of investigational drug products used in Oral Immunotherapy (OIT) treatments. The successful candidate will manage the supply chain activities for investigational medicinal products (IMP) and clinical trial materials (CTM) used in Aimmune clinical and non-clinical studies.

The core responsibilities include management clinical supply chain 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 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 US, the EU, and other regions and the demonstrated ability to work effectively in a virtual manufacturing environment are requirements for the position.

ESSENTIAL DUTIES:

- Ensure continuity of supplies for assigned studies and projects by managing distribution activities for Aimmune clinical studies, troubleshoot depot to site shipments, continuously monitoring inventories with demand and manufacturing forecasts Interface with internal and external contacts as required.
- 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 for clinical study drug and other drug supply as required (GLP, non-GLP non-clinical), including label copy, packaged product specifications, product shipping and storage specifications.
- Develop and maintain IRT/IXRS systems by working with Clinical Operations and outside vendors to design and implement the IRT/IXRS system used to automate the distribution of IMP/CTM to drug depots and clinical sites
- 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 & 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 3years professional experience, or equivalent experience, in pharmaceutical/biotech industry and two years minimum experience with IMP/CTM supply management.
- Experience in managing complex distribution IMP/CTM supply chains for double-blinded, placebo-controlled clinical trials in multiple geographies
- Understanding of ICH guidelines, global label development regulations and guidelines governing conduct of clinical studies a must
- Demonstrated working knowledge of international regulations governing transport and distribution of CTM materials
- Flexibility to travel on company business as required

Special skills/knowledge:

- Excellent written and verbal communication skills.
- Strong interpersonal skills and ability to function in a dynamic cross-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.
- Familiar with IMP labeling requirements and QP release process.
- Familiar with Annex 13, 15 & 16 as well as 21CFR a must and CSCP/CPM or similar is a plus.
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- Experience with GMP manufacture of drug products for clinical use is a plus.
- Broad exposure to multiple dosage forms is a plus.