Manager, Clinical Supplies

Position Summary:

This role is responsible for organizing all activities involved with the management of clinical supplies, which include packaging/labelling, global distribution, oversee implementation Interactive Response Technology (IRT), reconciliation, and destruction of clinical supply materials. This role reports to the Clinical Supply Chain Director.

Duties and Responsibilities:

- Ensure clinical labelling, packaging, and distribution needs for Trevi's clinical trials occur in a timely and cost-effective manner.
- Review labelling/packaging/distribution records in collaboration with QAC and vendor.
- Oversee inventory at depots and locations worldwide, including order management, logistics for returns or destruction, and distribution.
- Collaborate with the Clinical Team and Clinical Research Organizations in the development and implementation of the IVRS/IWRS (or other IRT).
- Collaborates with cross-functional study team members to ensure compliance of department/study activities with ICH guidelines, GxP, FDA and other applicable country regulations.
- Track clinical supply budget and manage costs related to packaging, labeling, and distribution.
- Work with Quality Assurance and Regulatory Affairs to identify, communicate and resolve potential quality issues arising during clinical trials.
- Maintain essential records in Trial Master File (TMF) and ensure audit readiness.
- Additional duties as needed.

Qualifications:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skills, and/or abilities required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Education and Experience:

- Bachelor's degree in Life Sciences, Pharmacy, Supply Chain, or related field.
- 5+ years of experience in clinical supply management within biotech/pharma/CRO.
- Strong understanding of clinical trial processes and regulatory requirements.
- Experience with IRT systems, supply forecasting tools, and inventory management.
- Experience with global clinical trials.
- Familiarity with SOP development and process improvement initiatives.

Competencies:

- Able to read, comprehend, write, and speak English fluently

- Excellent written and verbal communication and interpersonal skills. Able to communicate complex information clearly and succinctly, both in writing and orally.
- Strong influencing, negotiating and problem-solving skills, including across functional, geographical and cultural boundaries.
- Ability to collaborate effectively with cross-functional teams and external partners.
- Proficiency in Microsoft Office (Word, Excel, PowerPoint, Outlook) is also required.
    - Experience with MS SharePoint is preferred
- Excellent organizational and problem-solving skills.
- Must be able to work independently with minimal supervision.

PHYSICAL AND VISUAL REQUIREMENTS:

While performing the duties of this job, the individual is regularly required to use computers and office equipment, manipulate documents, and work in an office environment and work remotely from home as needed. The individual will experience prolonged periods of sitting and will also be required to talk or hear, reach with hands and arms, walk, bend, and stand frequently and may occasionally move materials up to 15 pounds. Limited travel may be required to support the duties of this position. The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Note:

This job description in no way states or implies that these are the only duties to be performed by the employee(s) incumbent in this position. Trevi reserves the right to modify, change or add to the position's job duties and responsibilities as business needs may require. This document does not create an employment contract, implied or otherwise, other than an "at will" relationship.

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