
Pharmacist

SPAULDING CLINICAL aims to be the clinical research organization by which all others are measured. Pioneering in our approach to redefining how the industry perceives and achieves success; passionate in our pursuit of ingenious solutions that mitigate risk; loving in our care for our volunteers, customers and employees; and heroic in our ambitions to ensure the health and safety of people around the globe - Spaulding Clinical is taking *research beyond results* to create a marketplace of safer drugs.

Original Date: 30 Apr 2012

Revision Date: 04 Jan 2018

Job Summary:

Ensures the accuracy of investigational drug storage, dispensing and accountability activities in the conduct of clinical trials at Spaulding Clinical. Assists the Director of Medical Operations in directing other Spaulding Clinical personnel who perform preparation, dispensing and documentation functions as necessary for specific studies. Perform all medication management services in compliance with protocol, Standard Operating Procedures (SOPs), regulatory guidelines, and Pharmaceutical client's needs.

Essential Duties and Responsibilities:

- As per the delegation log, manages the drug preparation, documentation, administration, and inventory of study drug.
- Communicates and interacts with Sponsors directly on issues of drug shipment and dispensation.
- Tracks drug inventory and orders drug supply from Sponsor.
- Meets with Clinical Research Coordinator and/or other pharmacy/nursing staff to review study medication dispensing procedures and needs for each study.
- Directly dispenses study medication as necessary or works in conjunction with the Clinical Operations staff and coordinators to do so.
- Ensures proper blinding/randomization of study medication and acts as the un-blinded party when necessary for the dispensing of study medication.
- Works in conjunction with the Clinical Operations staff and Coordinators on the preparation of labels and drug accountability forms for studies.
- Ensures proper drug storage, drug accountability and record keeping (e.g., temperature logs, etc.) as well as ensuring proper transportation conditions occurred between manufacture/packager and clinical site.
- Meets with the Clinical Research Coordinators as needed prior to study initiation to review study medication pharmacology, key issues, and plans.
- Contributes toward the creation, development, and implementation of department-wide initiatives including SOPs, and functional improvement initiatives

- Participates in quality assurance of clinical research projects and initiates the need for same as it impacts on clinical/pharmacy practice.
- Participates and collaborates in the presentation of reports and abstracts research proposals while actively involved in pertinent professional organizations.
- Readily accepts responsibility and is accountable for own and delegated activities.

The Statements made in the job description are intended to describe the general nature and level of work being performed by people assigned to this job. These statements are not intended to be an exhaustive list of all responsibilities, duties and skills required of people assigned to this job.

Skills/Qualifications

- Ability to read, write, and interpret the English language.
 - Demonstrates strong analytical, problem solving skills
 - Strong written and verbal communication skills and ability to effectively communicate with Pharmaceutical Sponsors and Clients
 - Self motivated, detail oriented, good organizational traits.
 - Must be results oriented, multi-tasking, quick learner, respond to the urgent needs of the team and show a strong track record of meeting deadlines.
 - Exceptional computer and specifically Office 2003 or later skills; inclination to adopt technology to maximize efficiency
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Physical Demands:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of the job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Ability to sit, stand, walk, reach with hands and arms, and use hands along with fingers, to handle or feel.
 - Ability to lift and/or move up to 25 pounds.
 - Specific vision abilities required by this job include clarity of vision both near and far.
 - Ability to identify and distinguish colors.
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Hazards:

- Potential for exposure to toxic or caustic chemicals
 - Potential for exposure to blood borne pathogens
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Education and Experience:

Job Description

- Registered Pharmacist with preferably a minimum three years of hospital or industry-sponsored clinical trials experience. Advanced degree preferred.
 - Valid Wisconsin Pharmacist License
 - Required broad knowledge of clinical research and drug development
 - Success in independent clinical project management preferred
 - Specific and in-depth knowledge of ICH GCP and 21 CFR
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Spaulding Clinical Research management has the discretion to hire personnel with a combination of experience and education which may vary from the above listed skills and qualifications.

This is to acknowledge that I have read and understand the above job description. This copy supersedes any others previously distributed. I further understand that Spaulding Clinical may change, add or delete any essential duties and responsibilities described at its discretion with or without prior notice.

Employee Name (Printed)

Date

Employee Signature