
Pharmacy Manager

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: 01 Mar 2019

Revision Date:

Job Summary:

Responsible for the overall oversight and complete documentation regarding investigational drug receipt, storage, dispensation and accountability activities in the conduct of clinical trials at Spaulding Clinical while demonstrating the ability to provide consistent direction for all pharmacy related personnel in planning, organizing, implementing and evaluating clinical research activities. Performs all medication management services in compliance with protocol, Standard Operating Procedures (SOPs), regulatory guidelines, and pharmaceutical client's needs. Management of departmental employees: responsible for directing and scheduling workload, completing performance appraisals, administering employee related policies, and ensuring compliance with company policies.

Essential Duties and Responsibilities:

- Under the supervision of the Director of Clinical Operations, oversees and manages the pharmacy and staff in regard to drug preparation, administration, and inventory.
- Responsible for all pharmacy-related protocol review, risk management and mitigation planning, as well as Pharmacy Manual creation or approval for all contracted study activity.
- Keeps abreast of SOP's, ICH/GCP guidelines, NIH guidelines, as well as state and national regulatory requirements.
- Available and prepared for Sponsor, CRA, and/or customer pharmacy meetings, audits, monitoring visits.
- Responsible for creating, maintaining, and filing study Pharmacy binder completely and accurately.
- Monitors each report's training throughout their training period and makes recommendations regarding progress of the individual.
- Is present and available onsite to staff during business hours, as well as available by telephone and/or email for urgent needs during non-business hours.
- Keeps employees updated on important issues and company objectives through scheduled department meetings and assigns action items, while staying united with Clinical Operations management on quarterly/yearly goals.

- Periodically monitors procedures and study specific events to ensure they are being followed correctly and staff is demonstrating competence.
- Holds 1:1 Meetings with all reports on regular basis for oversight, feedback, and career development purposes. All Full-Time and Regular Part-Time staff will have documented 1:1's on a monthly basis. Pool staff will have documented 1:1's on a quarterly basis.
- Supervises departmental employees: responsible for directing and scheduling workload, completing performance appraisals, administering employee related policies, and ensuring compliance with company policies.
- Monitors and reviews all PTO requests, ensuring coverage for all departmental needs.
- Responds with appropriate level of urgency to issues raised by staff, prioritizes importance, and resolves issue or delegates as appropriate.
- Mentors, trains, and supervises clinical staff in order to promote growth of each individual, whether in job progression or mastering a set of skills.
- Specifically monitors and contributes oversight and metrics associated with this department, as requested by Manager.
- Interacts with other functional managers across multiple areas to facilitate smooth work processes and communication throughout the study process.
- Supervises tracking/management of trial progress for Pharmacy, in order to ensure that trials are completed per protocol, in accordance with Spaulding and Sponsor project goals, and in accordance with ICH GCP, 21 CFR, and other applicable laws/regulations
- Assists with managing study budgets to ensure that internal/external operating costs are closely managed as they pertain to pharmacy departments.
- Ensures that all pharmacy and dosing-related supplies are properly ordered and onsite prior to need.
- Collaborates with Quality Department to own, develop, maintain, and ensure training and compliance with departmental SOPs and Work Instructions.
- Responsible for departmental Quality Metrics and timely reporting of metrics data and presenting of data during management review, as requested by Manager and QA.
- Ensures timely investigation and completion of CAPA's.
- May assist in departmental internal audits.
- Collaborates with HR Department to develop, review, and revise departmental job descriptions.
- Collaborates with HR Department on departmental staffing (hiring/transfers/promotions)

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.
- Demonstrated ability to lead by example and to encourage team members to seek solutions
- Excellent planning and organizational skills
- 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.
 - Exceptional computer and specifically Microsoft Office skills; inclination to adopt technology to maximize efficiency
 - Must be results oriented, multi-tasking, quick learner, respond to urgent needs of the team and show a strong track record of meeting deadlines.
 - Basic knowledge and understanding of Quality Systems (SOPs, WI's, CAPAs, and internal audits).
 - Basic knowledge and understanding of Employment Laws (FLSA, FMLA, ADA, hiring, termination, and harassment)
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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:

- Registered Pharmacist or Physician with preferably a minimum three years of hospital or industry sponsored clinical trials experience. Advanced degree preferred.
- Valid Wisconsin professional License
- Requires 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.

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.

Job Description

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