
Charge Staff

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: 16 Apr 2012

Revision Date: 02 Nov 2015

Job Summary:

Responsible for overseeing daily clinical operations on clinical study floor and ensuring all studies are conducted according to study protocols and Spaulding Clinical SOP's. Works closely with Clinical Research Coordinators, Clinical Staff Manager and Clinical Floor Supervisors to ensure studies are conducted according to study specific operational plans. Coordinates, organizes, monitors and delegates daily activities of Clinical Staff assigned to study floor events, ensures adherence to policies and procedures and provides leadership and professionalism in clinical problem solving.

Essential Duties and Responsibilities:

- Keeps abreast of SOP's, ICH/GCP guidelines, NIH guidelines, as well as state and national regulatory requirements.
- Maintains calm, professional atmosphere on study floor, leading by example with professional resolution of conflict and appropriate delegation.
- Ensures that Clinical Staff Manager and Clinical Floor Supervisors are updated and aware of any issues that arise on the study floors.
- Records subjects Adverse Events with proper documentation and treatment as warranted and escalates to medical personnel or CRC's as appropriate.
- Ensures all shift duties are completed according to Charge Checklist or equivalent, including completion of all applicable logs and metrics.
- Escalates study related issues to Clinical Staff Manager, Clinical Floor Supervisors and Clinical Research Coordinators with urgency if needed. Communicates all other issues as warranted with Clinical Operations Manager, Principal Investigator, Pharmacist, and/or IT.
- Works with colleagues to achieve departmental goals as delegated.
- Maintains knowledge of company goals to assist all floor staff in their development and engagement.

- Accepts accountability to lead the clinical team with the highest level of professionalism and communication strategies.
 - Maintains a clean, quiet study environment in all study areas.
 - Works with Training Department to perform and document Process Monitoring to ensure staff compliance and adherence.
 - Accepts other responsibilities as needed/assigned for Process Preceptor, Sub-Process Owner, and/or Lead Charge.
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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.
 - Fully trained to advanced position (Nurse, Technician, etc), or is underway.
 - Must show ability to stay up-to-date on all available trainings.
 - Excellent time management skills.
 - Demonstrates strong analytical and problem solving skills.
 - Demonstrates effective leadership traits with ability to direct and delegate.
 - Portrays professionalism in all interactions at Spaulding Clinical.
 - Strong written and verbal communication skills.
 - Possess good organizational traits.
 - Self-motivated.
 - Must be reliable and responsible for attending scheduled shifts, along with flexibility for higher study activity demands.
 - Must be results oriented, proficient at multi-tasking, quick learner, responsive to the urgent needs of the team and show a strong track record of meeting deadlines.
 - Good computer skills; inclination to adopt technology to maximize efficiency.
 - Strong attention to detail.
 - Demonstrates ability to adapt to a rapidly changing study environment.
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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.

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- 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:

- Medical background required, with skill set appropriate for role
 - Must be trained (or in-training) as Clinical Research Technician - Advanced or Clinical Research Nurse - Advanced
 - Has demonstrated effective professionalism, leadership, and problem-solving skills as clinical floor staff for approximately 6 months at Spaulding Clinical, **OR** exceptional outside experience (previous charge, supervisory and/or leadership position) that would translate to a Charge role immediately upon hire
 - CPR certification required within one year of hire or promotion date
 - ACLS certification required within one year of hire or promotion date
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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