Project 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: 20 Aug 2019

Revision Date:

Job Summary:

Responsible for the management and oversight of activities from start-up to close-out related to the conduct of multiple clinical trials with emphasis on Spaulding Clinical's SOP's, regulatory guidelines, quality, and protocol adherence.

Ultimate responsibility for proper protocol execution and timeline management resides with this Project Manager position.

Manage the daily work of designated Associate Project Managers (APM's) and other support staff by overseeing adherence to SOP's, Work Instructions, Good Clinical Practice (GCP), FDA regulations, and each individual study protocol. Able to provide prompt and thorough review (with appropriate feedback) on all study documents created by the APM.

Extensive familiarity with a variety of the industry concepts, practices, and procedures. Relies on wide-ranging experience and judgment to plan and accomplish goals of high-quality outcomes.

Leads and directs the work of the APM's working on basic, standard, and/or complex clinical research trials. Responsible for customer satisfaction in regard to protocol adherence, operational excellence and quality, team cohesiveness, and proper study execution.

Always present for customers (sponsors) by being available for site visits, teleconferences, and able to provide tours. Willing and able to provide excellent customer service for all sponsors, their representatives, CRAs, etc. Goal and expectation is to ensure customer satisfaction and repeat business.

Responsible for continued training for those new to the Associate Project Manager role, works as an available resource for entire Project Management team on regulatory, SOP, and various Phases of study information. This includes creating and utilizing training materials that enhance and fulfill the complex responsibilities needed in the Associate Project Manager role.

Essential Duties and Responsibilities:

- Acts as principal liaison between Sponsor and Spaulding Clinical Research (and in close collaboration with Principal Investigator and Medical Operations team)
    - Provides timely and accurate information to Sponsor – acts as specialist for the customer, making their experience smooth
    - Maintains professional working relationships with Sponsor representatives and colleagues within Spaulding Clinical Research
    - Manages timelines and provides updates as needed to all team members – Documents all project deliverables and ensures appropriate time schedule is achieved
    - Leads Sponsor meetings and teleconferences – acts as the "face to the customer"; ensures agenda, meeting minutes and action items are properly completed
    - At study award, responsible for establishing communications with the pharmaceutical sponsor, and initiating study setup.
    - Develops various project plans and ensures optimal quality of all projects and prepares schedule while managing all resources
    - Initiates and oversees a comprehensive Risk Management exercise and Internal Kickoff Meeting to identify and mitigate study risks for all team members.
- Promotes effective inter-departmental relationships; encourages cross-functional cooperation.
    - Develops Leadership skills to increase customer and employee satisfaction.
    - Aligns self and actions with Goals per business and objectives by:
        - being open and accepting of change,
        - increasing professionalism (colleague relationships, customer service, using time productively, able to appropriately delegate)
        - displaying operational excellence (job knowledge, focus on quality, problem-solver, lack of protocol deviations within Project Management Team)
    - Coordinates with Finance and Contract teams to design all financial projections and ensure project stays on budget.
    - Acts as trainer, mentor, and coach to all Project Management team staff.
    - Responds to employees in a professional, timely and thorough manner. Seen as a calm responder to tense business situations; able to de-escalate others' behavior and inspires other team members
- Throughout the study, ensures that all study activities are executed per the study protocol, regulatory guidelines, and operational/project plan.
    - Reviews Investigational Drug Brochures, Protocols, Case Report Forms (CRFs), and informed consent forms for a thorough understanding of the study drug and procedures.
    - Keeps abreast of SOPs, Good Clinical Practice (GCP) and ICH guidelines, state and national laws and ethical standards.
    - Supports the development and management of project-specific Essential Documents. This includes preparation, tracking, documented quality control and quality assurance, then maintenance and final disposition for the TMF.

  - Provides clinical support for data management (Biometrics) by resolving any data queries and clarifying data queries as requested and by timeline.
  - Reviews all site and Sponsor communications for clarity and accuracy.
  - Conducts a close-out inventory of clinical supplies, materials, pharmacy supplies, and coordinates the return of unused materials per Sponsor instruction.
- Participates in quality assurance of clinical research studies and initiates the need for same as it impacts on clinical practice.
  - Provides feasibility impact advice during contracting period to ensure accuracy of quotes and ability to perform
  - Provides required metrics to Manager on a timely basis
  - Assists QA department by performing quality audit procedures, including investigation of study files, collected data and clinical forms.
  - Responsible for updating current processes and contributing to new processes in order to streamline activities. This includes providing training plans to ensure gained knowledge and compliance.

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, organizational, and time management skills
- Excellent oral, written and presentation skills
- Demonstrates strong analytical, problem solving skills
- Strong written and verbal communication skills, with many different departments and personality types.
- Detail oriented.
- Self-motivated
- 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.
- Good computer 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.

Hazards:

- Potential for exposure to toxic or caustic chemicals
- Potential for exposure to blood borne pathogens

Education and Experience:

- Bachelor's Degree in Nursing, Healthcare Management, Business or related field, preferred
- Minimum of four years as Phase 1 project management experience, required
- Possesses the leadership skills to effectively direct employees while in a training environment and ability to properly evaluate comprehension and application of material
- ACRP (or equivalent) certification, preferred
- PMP (or equivalent) certification, preferred
- Demonstrated "Good Clinical Practices" and regulatory knowledge (ICH-GCP)

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 _____