spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

PK Sample Coordinator

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: 11 July 2012

Revision Date: 16 Feb 2018

Job Summary:

Responsible for the day to day oversight of tasks in the PK Laboratory. This individual will work closely with other Clinical Operations management to ensure the department is meeting organizational and quality goals. Accountable for coordination of all pharmacokinetic (PK), pharmacodynamics (PD), and/or pharmacogenomics (PG) samples for all clinical pharmacology studies. Also, accountable for sample tracking metrics, creating study-specific PK Procedure Plans, and other start-up tasks that safeguard the high quality of a clinical trial. Answerable for actions that guarantee that the planning, supply ordering, and labeling of collection and assay tubes are prepared accurately. This also involves ensuring that protocols, SOP's, quality control, and regulations are all followed in the process.

Essential Duties and Responsibilities:

- Reviews protocols and available Lab Manuals for a thorough understanding of the study drug and all sample processing procedures.
- Responsible and accountable that all PK Lab-related quarterly business goals are achieved, or adjusted with management input.
- Responsible and accountable for scheduling of all PK Lab staff, including timely trainee planning. Ensures that the staffing schedule is prepared and submitted to Clinical Staffing Coordinator by deadline. Able to provide information regarding staffing needs, to protect the processes of the lab.
- Creates accurate and detailed study-specific PK Procedure Plans and other items related to study set-up, and ensures proper implementation and training for staff.
- Responsible and accountable for performing (or delegating) proper and timely Build Review for Screening/Main Session Activity Plans, according to deadline. Submits changes and finalizes review per deadline.
- Responsible and accountable for the planning, supply ordering, and labeling of collection and assay tubes for all study PK, PD, and/or PG samples. Ultimately responsible that all tubes are correctly labeled in appropriate amount of time prior to study floor/Screening/OPV need.

- Ensures that a risk management exercise is performed for each study, and the points are addressed/mitigated prior to study start-up.
- Contributes to and is accountable for the secure and appropriate storage of all labeled tubes and PK, PD, and/or PG samples (primary and back-up samples). This includes, but is not limited to documentation as follows:
    - Completion of Shipment Spreadsheet for ALL PK, PD, PG samples – this includes both primary shipments as well as back-up shipments.
    - Accurate documentation within the temperature monitoring system to indicate appropriate storage location and temperatures were maintained. Any changes are to be completely explained within the system in an audit-ready format.
- Responsible and accountable for planning, accuracy, documentation, and timeliness of all packaging and shipments of PK, PD, and/or PG samples.
- Responsible and accountable to maintaining accurate records of sample manifests and produces summaries/metrics of any sample tracking deviations. Provides these records to KPI and Study Summary sheets, and to CRC for Deviation Log by required deadlines.
- Leads PK Lab staff in regard to professionalism, performance, and/or attendance issues. Documents using Coaching Forms and escalates to Laboratory Manager appropriately.
- Prepares, trains, and executes to any needed Runner schedules for each study.
- Keeps abreast of SOPs, Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Bloodborne Pathogen (BBP), OSHA, and ICH guidelines, state and national laws and ethical standards.
- Ensures effective verbal and written communications inter- and intra-departmentally in the planning and implementation of clinical research studies.
- Responsible for all sample processing, to ensure procedures are followed appropriately.
- Ensures all Clinical Research Sample Specialists and Clinical Interns are training to new processes, equipment, and procedures. This must all be documented properly.
- Ensures that (along with Supply Manager and QA) that all periodic maintenance on equipment is completed on time, and is well-documented.
- Ensures that PK lab staff are completing all daily, weekly, monthly, and as-needed cleaning in the lab.
- Periodically assesses and analyzes all procedures related to sample collection, processing, storage and shipment, by direct observance of procedures, and suggests solutions to process issues.
- Ensures that CRSS-Advanced, CRSS-Basic, and Clinical Interns are scheduled appropriately to tasks relegated to the role.
- Maintains inventory for any needed supplies, ahead of need.
- Required to be present at business-dictated hours, primarily the AM shift and PM as needed.
    - Needs to be available and able to report on critical deadlines, daily updates, metrics during departmental meetings.
    - Overtime is expected, and may be required, in times of high occupancy or tight deadlines.
    - Is available and willing to work CRSS shifts that cannot be covered so that no study shift is left understaffed.

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.
- Excellent Time Management Skills
- Proficient at multi-tasking
- Phlebotomy Skills Preferred
- Demonstrates strong analytical, problem solving skills
- Strong written and verbal communication skills.
- Detail oriented, good organizational traits.
- 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 and is inclined to adopt technology to maximize efficiency

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
- Potential for exposure to dry ice

Education and Experience:

- High School Diploma or GED equivalent, required
- Demonstrated knowledge of "Good Clinical Practices" and “Good Laboratory Practices required
- Laboratory experience required

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