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## Clinical Research Sample Specialist - Advanced

**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.

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Original Date: 19 Sep 2013

Revision Date: 23 Sep 2015

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### Job Summary:

Responsible for basic technical PK and clinical laboratory procedures activities (such as, but not limited to, PK runner and splitter, PK tube labeling, tube sorting, urine collection, height/weight/BMI, laboratory testing procedures, PK shipping) in the conduct of clinical trials with emphasis on the safety and welfare of study participants. Performs the practical activities of clinical studies according to protocol, regulatory requirements, SOPs, scope of practice and current training status.

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### Essential Duties and Responsibilities:

- With supervision, ensures that clinical trials are conducted according to protocol requirements by utilizing the following techniques & procedures.
- Performs proper and accurate sample management, including transport, and/or processing of biological (blood, urine, etc) subject samples.
- Performs proper and accurate urine sample collection and identification.
- Performs and records physical measurements including height, weight, and BMI calculation.
- Appropriately and accurately generates/applies specimen labels for safety lab, PK sample, and/or aliquot samples.
- Documents all sample processing accurately within associated computer systems
- Centrifuges and prepares aliquots for protocol-specified storage and proper sorting of samples
- Maintains specimen requirements at all times according to protocol
- Performs CLIA-waived laboratory testing according to procedure
- Pipettes plasma/serum efficiently, safely, and accurately
- Maintains all laboratory standards, according to practice
- Maintains IATA/DOT shipping standards, as supervised by PK Sample Coordinator
- Reviews Study Specific Trainings and applicable protocols for a thorough understanding of the study procedures, as they apply to their role and ensures that Delegation of Authority/Training Log for each study is completed in a proper and timely manner.

- Keeps abreast of SOPs, Good Clinical Practice (GCP) and ICH guidelines, state and national laws and ethical standards.
- Observes and maintains all HIPAA, OSHA, and Exposure Control regulations and Emergency Response as required by applicable training.
- Creates and maintains accurate records of all protocol activities and events, as delegated and trained.
- Follows progress of volunteers and provides for their care, comfort and safety by attending to their needs during study participation.
- Participates in quality assurance of clinical research projects and initiates the need for same as it impacts on clinical practice.

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.

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### **Skills/Qualifications**

- Ability to read, write and interpret the English language.
  - Portrays professionalism in all interactions at Spaulding Clinical.
  - Laboratory skills and technique in aliquoting plasma, urine and stool samples
  - Laboratory testing experience preferred; knowledge of CLIA requirements
  - Strong computer skills; inclination to adopt technology to maximize efficiency
  - 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.
  - Ability to work beyond normal work hours and various shift availability required.
  - Ability to perform and record data entry via computer systems while conducting timed clinical procedures.
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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
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**Education and Experience:**

- Associate's Degree in a scientific/medical discipline desirable
  - Laboratory experience highly desirable
  - CPR 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.*

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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.

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Employee Name (Printed)

\_\_\_\_\_  
Date

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Employee Signature