
Laboratory Assistant

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: 02 Sep 2020

Revision Date:

Job Summary:

Under general supervision, the Laboratory Assistant performs specimen processing, receives and sorts specimens and performs computer data entry. Will staff and perform test analysis per training and scope, following all CLIA, FDA, and OSHA regulations. Functions as a liaison between the PK Laboratory, Clinical Laboratory, and internal CPU customers. This role will report to the Technical Supervisor/Consultant and will perform daily task direction, as required per laboratory business needs.

Essential Duties and Responsibilities (may include):

- With supervision, ensures that clinical trials are conducted according to protocol requirements by utilizing the following techniques & procedures.
- Trains to and performs (with supervision) tasks such as:
 - PK or Clinical Laboratory tube labeling
 - performance and documentation of CLIA-waived or EUA testing, per training and scope of work
 - ensures that specimens received into PK or Clinical Lab are properly labeled and suitable for testing. Resolves specimen identification and/or requisition problems and clarifies requests
 - processes specimens for testing, including aliquoting, while maintaining proper specimen identification
 - enters and verifies test requests into the laboratories' computer system to allow for analysis and timely turn-around-time for results
 - and inventorying supplies in laboratory or study areas,
 - answers and screens telephone calls
 - receives and sorts specimens and assists with detailed specimen handling; packages and tracks specimens for transport and performs specimen storage and retrieval
 - scanning, saving, and/or filing of documents,
 - organizing and sorting PK or Clinical Laboratory samples,

- PK Lab “Runner” duties,
- technological entry of needed laboratory data
- performance of study events following training and proficient competency assessment,
- Other Clinical Pharmacology tasks on this level, as assigned
- 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, if indicated.
- Keeps abreast of SOPs, Good Clinical Practice (GCP) and ICH guidelines, state and national laws and ethical standards, as trained and delegated.
- Observes and maintains all HIPAA, OSHA, CLIA and Exposure Control (Bloodborne Pathogens) regulations and Emergency Response as required by applicable training.
- Creates and maintains accurate records of all protocol activities and events, as delegated and trained.
- 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.
 - Basic Computer skills
 - Demonstrates strong, analytical, problem solving skills
 - Self-motivated
 - Detail-oriented with strong organizational traits
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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:

- High School student or graduate (or equivalent certification)
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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