spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

Quality Assurance Specialist / Auditor

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: 17 Dec 2013

Revision Date: N/A

Position Reports To: Sr. Manager of Quality Assurance/Regulatory Affairs

Position Supervises: None

Job Summary:

Assist in planning, coordination, control, and continuous improvement of processes and methods to ensure conformance to internal and external quality and regulatory standards of studies conducted and product produced at Spaulding Clinical.

Essential Duties and Responsibilities:

- Lead Clinical auditing activities to ensure that studies are conducted in accordance with sponsor protocols, GCP, industry guidelines, agency regulations.
- Assist activities in the areas of Internal Quality Audits, CAPA (Corrective and Preventive Actions) and Production support.
- Schedule applicable training and update roles as needed. Configure and run required reports.
- Provide training during new hire orientation on standard training needs and use of our training system
- Lead or assist with identifying non-conformances and provide suitable recommendations while maintaining compliance with applicable study protocols, Quality System Regulations and or ISO standards where applicable.
- Assist in conducting supplier audits and work with suppliers and production support personnel in eliminating problems via root cause analysis techniques, to ensure that product quality continuously improves.
- Track and review company metrics
- Support special projects requiring QA input.
- Perform other related duties as assigned.

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.
- Demonstrates strong analytical, problem solving skills.
- Strong written and verbal communication skills.
- Detail oriented, good organizational traits.
- Self-motivated, with strong leadership abilities.
- 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.

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.

Hazards:

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

Education and Experience:

- Associated degree required, bachelors degree preferred.
- At least 3 years experience in the Pharmaceutical Industry and or Medical Device Industry with an understanding of ICH Guidelines and GCP and other international regulatory requirements for the conduct of clinical trials.
- Three plus years QA, GMP and/or GCP auditing
- Three plus years working in a Quality Control / Assurance area.
- Experience and knowledge of medical device Quality System Regulations or ISO Standards.
- Must know, facilitate and maintain GCP/ICH compliant processes which control the quality of work and clinical trials conducted at Spaulding Clinical.

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.