

Clinical Quality Assurance 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: 23 Sep 2010

Revision Date:

Position Reports To: Vice President of Quality Assurance

Position Supervises: Clinical QA Staff

Job Summary:

Responsible for the Clinical Quality Assurance functions of the organization reporting to the V.P of Quality Assurance. Ensuring planning, coordination, control, and continuous improvement of processes and methods are established to control the quality of studies conducted at Spaulding Clinical. Lead a team focusing on continuous improvement projects using approved tools, design control, validations, and ensuring adherence to the agency regulations, GxP, Industry Guidelines, local regulations, along with Spaulding Clinical policies and procedures for the conduct of clinical trials. This involves working closely with Clinical Operations, Information Technology, and other supporting areas/development teams, to help ensure active participation in continuous quality improvement activities.

Essential Duties and Responsibilities:

- Develop and maintain GCP/ICH compliant processes which control the quality of work and clinical trials conducted at Spaulding Clinical.
- Actively lead or assist activities in the areas of Internal Quality Audits, CAPA (Corrective and Preventive Actions), Production support, Quality Management Reviews, and Quality Audits.
- Lead auditing activities to ensure that studies are conducted in accordance with sponsor protocols, GCP, industry guidelines, agency regulations.
- Lead or assist with identifying non-conformances with requirements, provide suitable recommendations and facilitate ongoing quality improvements using risk-based methodology while maintaining compliance with applicable study protocols, Quality System Regulations and or ISO standards where applicable.
- Assist with management of contract auditors.
- Assist in conducting vendor audits and work with vendors and production support personnel in eliminating problems via root cause analysis techniques, to ensure that product quality continuously improves.
- Assist in providing training to Spaulding Clinical staff.
- Participate in the review and installation of technology products and equipment.

Job Description

- Review vendor supplied data and quality records for conformance and good documentation practices (GDP).
- 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

- 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.
 - 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:

- Bachelors Degree or equivalent experience in associated functional discipline.

Job Description

- At least 3 years experience in the Pharmaceutical Industry and or Medical Device Industry with an in-depth knowledge of US, EU and International regulatory standards, and GxP Guidelines for the conduct of clinical trials.
 - Five plus years working in a Quality Control / Assurance area.
 - Experience and knowledge of medical device Quality System Regulations or ISO Standards.
 - ASQ, Auditor, Clinical Trial Associate or Clinical Trial Manager accreditation highly desirable.
 - Experience including external/CRO, clinical/regulatory and document auditing highly desirable.
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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.