
Medical Director / Associate Medical Director

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: 15 Feb 2009

Revision Date: 11 Mar 2011

Position Reports To: General Manager & Senior Vice President of Operations

Position Supervises: None

Job Summary:

Provides the appropriate medical direction, strategy and coverage for Spaulding's Clinical Pharmacology services. As needed, acts as Principal Investigator/Sub-Investigator and is responsible for assuring the health and welfare of study participants. Responsible for performing/overseeing medical procedures and responsible for proper conduct of the study trials and their associated trial-related medical decisions. Works closely with Spaulding's Chief Medical Officer and Pharmaceutical Sponsors to ensure complete medical continuity throughout the research process.

Essential Duties and Responsibilities:

- Provide medical review of safety protocols, and clinical brochures as requested by sponsors.
- Responsible for protecting the rights, safety and welfare of study participants under their care.
- Responsible for ensuring that the clinical trial is conducted according to the investigational plan and all applicable regulations.
- Provide medical and scientific feasibility of all new sponsor inquiries via of protocols and provide clinical and scientific support.
- Interact with regulatory bodies as relevant to clinical operations.
- Attend study initiation meetings and present protocols at IRB meetings, as required.
- Assist Clinical Operations and Client Managers with sponsor visits.
- As needed perform medical evaluations to ensure volunteers are medically and mentally fit upon entering the study.
- Inform Principle Investigator, IRB and Sponsor as appropriate of relevant events.
- Delegate the above as appropriate.

- Act as Principle Investigator/Co-Investigator as assigned.
- Weekend and off-hours work as necessary

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.
 - Strong written and verbal communication skills.
 - Detail oriented, good organizational traits.
 - Strong interpersonal and leadership skills, self-motivation, and high personal integrity and ethics required.
 - Experience with FDA inquiries involving drug safety including the ability to review safety and labeling protocols.
 - Familiarity with the FDA organization
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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.
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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:

- M.D. or Doctor of Osteopathic Medicine
- U.S. Board Certification
- Active license to practice medicine in the state of Wisconsin, or an active license that is transferable to Wisconsin within 3 months.

- 5 years M.D. experience
 - Minimum of 3 years of clinical research experience within a private practice, academic medical, pharmaceutical sponsor, or CRO setting.
 - Experience with FDA inquiries involving drug safety including the ability to review safety and labeling protocols.
 - Familiarity with the FDA organization
 - Strong interpersonal and leadership skills, self-motivation, and high personal integrity and ethics required.
 - DEA license
 - Specialty in Internal Medicine, Emergency Medicine, or Family Medicine
 - Clinical research experience within a CRO or Phase 1 research facility
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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