

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.

Business Title **Associate Medical Director**

Job Description Provides medical coverage for the Clinical Site. As Principle Investigator/Sub-Investigator, responsible for assuring the health and welfare of study participants. Responsible for performing medical procedures, responsible for proper conduct of the study trial, and responsible for all trial-related medical decisions. Monitor and summarize clinical adverse events; maintain all aspects of medical safety for studies at the research site. Provide medical review of safety protocols, and clinical brochures as requested by sponsors.

Duties and Responsibilities:

- 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.
- Direct test article administration or dispensation.
- Review and evaluate protocols and provide clinical and scientific support.
- Liaise with sponsor regarding study design and site capabilities.
- Interact with regulatory bodies as relevant to clinical operations.
- Attend study initiation meetings.
- Present protocols at IRB meetings, as required.
- Assist Clinical Operations and Client Managers with sponsor visits.
- Perform pre-study physical examinations and review lab data to ensure volunteers are medically and mentally fit upon entering the study.

- Perform on-study and post-study physical examinations to ensure that the physical and mental well being of volunteers is undiminished at the end of the study.
- Inform Principle Investigator, IRB and Sponsor as appropriate of relevant events.
- Review and sign CRFs at the conclusion of the study.
- Delegate the above as appropriate.
- Act as Principle Investigator/Co-Investigator as assigned by the Medical Director.
- Weekend and off-hours work as necessary.

**Required Education
/Qualifications**

- 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.
- 3-5 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.

**Preferred Education
/Qualifications**

- DEA license
- Specialty in Internal Medicine, Emergency Medicine, or Family Medicine
- Clinical research experience within a CRO or Phase 1 research facility
- Experience conducting Phase 1 clinical trials