Clinical Study Manager

Location: Ottawa, Greater Toronto Area, or anywhere in-between.

The Clinical Study Manager plays a lead role in the development, coordination and project management of clinical trials from protocol development through to ethics approval, activation, follow-up and closure. This role is responsible for projects involving various company initiated cardiovascular diagnostic device trials. The position will report to the company's Regulatory Affairs Director.

Duties

- Working with senior management and medical advisors to develop the company's clinical affairs strategy and clinical trial protocols
- Support clinical site recruitment and assessment of clinical sites for suitability
- Project management of both single and multi-centre studies
- Coordination of clinical trial / research protocol development, including case report, and informed consent forms, and amendments.
- In conjunction with study principal investigators, ensure compliance with all legal, contractual and protocol requirements related to clinical trials and clinical research
- Manage the site and investigator qualification process, device operator training, clinical monitoring program, and associated reporting
- Communicate with clinical study sites, principal investigators, physicians, nurses, research coordinators, external stakeholders and vendors
- Support regulatory submissions related to clinical trials and product registrations, and ensure studies are conducted in accordance with ICH-GCP, Health Canada, FDA as well as other regulatory requirements
- Apply quality assurance procedures, including those required under ISO 13485 and 21CFR Part 820, to ensure that high quality data is obtained and protected
- Collaborate with medical and scientific teams in the development of articles, posters, and whitepapers for presentation at conferences and publication in medical journals.

Qualifications

<u>Education</u>

- Undergraduate Science degree or recognized equivalent
- Strong understanding of biostatistics desired
- Clinical Research certification preferred
- Degree in nursing preferred

Experience

- Minimum 5 years' experience in medical device clinical trials management
- Clinical or medical science background

Skills & Functional / Technical Competencies

- Self-motivated with initiative, good judgment and the ability to multi-task
- Excellent organization and prioritization skills
- Able to work in a fast-paced environment while paying close attention to detail
- Able to problem solve and apply critical thinking
- Able to learn quickly and work independently
- Able to produce high quality work while meeting deadlines
- Able to work well independently and as part of a team
- Knowledge of applicable legislation and regulations (Health Canada, FDA, CE Mark)
- Demonstrated proficiency in English, with excellent oral and written communication skills
- Demonstrated proficiency in MS Office applications
- Valid driver's license

Work Location and Travel

The Clinical Study Manager will be required to travel regularly to sites in and between Ottawa and Toronto, primarily using their own vehicle (mileage reimbursed). As the company grows, additional travel may be required to other regions of Canada and the USA.

This role is suitable for someone located in the Ottawa area or who can work remotely out of Eastern Ontario or the Greater Toronto Area. If the successful candidate is not located in the Ottawa area, additional periodic travel to AusculSciences' Ottawa location will be required.

What's in it for you?

- A chance to help improve the health and well-being of people with cardiovascular conditions.
- The opportunity to make a difference within a close-knit but growing company.
- A competitive salary
- Comprehensive health, dental, paramedical, and death/disability benefits
- Generous vacation allotment
- Excellent work-life balance
- Opportunities for training and development
- A team lunch and general-knowledge quiz game on Fridays
- A modern workplace within the heart of Kanata North, with easy walking access to a number of restaurants, shops, and the extensive Beaver Pond Trail network

If you have the experience we are looking for, please forward your resume, and cover letter, to the attention of careers@ausculsciences.com. We thank all applicants for their interest. Please note that only candidates being considered for an interview will be contacted. AusculSciences will provide reasonable accommodation to persons with disabilities to allow you to participate in the recruitment process, upon request.