Position: Director/Sr. Director, Clinical Operations: Quality Systems and Process

JOB DESCRIPTION:

The Director, Clinical Operations, Quality Systems and Process (DCOQSP) will be responsible for supporting the planning, oversight and implementation of systems, process, and training to support the execution of clinical trials associated with multiple projects conducted by Heron, Quality improvement initiatives range from the development of clinical trial documents and selection and training of study sites, through the oversight of protocol implementation, data analysis and assembly of final study documents. The incumbent will provide support to achieve GCP, ICH, and Quality obligations. In addition, the DCOQSP will oversee document management and trial master file within Clinical Operations.

PRIMARY RESPONSIBILITIES:

- Responsible for periodic review of Clinical Operations SOPs and processes to insure the information is current, appropriate for the business, and fully implemented across the functions.
- Responsible for business owner input and oversight for systems such as Veeva, CTMS, EDC, and IWRS.
- Responsible for the Clinical Trial Assistant/Document management function within Clinical Operations.
- Selection, implementation, and training for systems supporting clinical operations work
- Development of onboarding programs for functions within Clinical Operations, and periodic refresher training.
- Provide guidance to clinical operations staff based on interpretation of current regulations to ensure best practices.
- Resolving operational, compliance or other problems impacting trial progress/quality.
- Functioning as lead advisor for site audits, including defining, scheduling, assessing and evaluating eventual outcomes.
- Identifying requirements and developing solicitations for clinical research activity providers such as CROs (data management, site oversight, monitoring), sites, and laboratories.
- Technical oversight of contracts supporting clinical trial activities.
- Assisting in the development of a comprehensive approach to coordination, harmonization and oversight of activities.
- Developing, populating and maintaining a database of information related to clinical trials including site lists, investigator lists, common protocol deviations, consultants/contractors, and other potential service providers.

- Providing project management expertise, as needed, to insure quality and timely completion of project milestones.

REQUIREMENTS:

- Master's Degree or higher strongly preferred in related scientific discipline (nursing, epidemiology, public health, etc.) although exceptions will be made for highly qualified candidates with extensive work experience.
- Minimum of 10 years of experience in leading and supporting clinical research (at various levels and in different capacities), including academic and/or industry experience in all phases of clinical research, supporting US as well as international trials.
- Knowledge of pharmaceutical and regulatory requirements, procedures, and policies with a minimum of 5 years of pharmaceutical experience.
- Knowledge of GCP, ICH, and other Guidance documents and policies related to clinical trials operations requirements.
- Knowledge of all aspects of clinical drug development (Phase 1-4).
- Ability to analyze information, review reports and prioritize actions.
- Excellent computer skills; strong verbal and written communication skills.
- Ability to work well in a team environment both as a leader and a contributor.
- Open, engaging, and transparent work style.
- Global perspective and mindset; ability to work effectively with colleagues from other cultures.
- Experience implementing protocols in an international setting, providing training and overseeing clinical research studies are all desirable.
- Ability to competently manage a very heavy workload and multiple competing priorities, switching priorities quickly as needs change. Must be comfortable working in a quick-paced environment.
- Demonstrated very high level of technical skill and expertise as pertains to clinical operations quality improvement.
- Demonstrated high proficiency in project planning and management and proactively anticipate and identify complex issues and problems.
- Demonstrated exceptional interpersonal skills and written and verbal communication abilities.
- Demonstrated excellent decision-making abilities with competency in making decisions and resolving problems. Ability to recognize which decisions may have a consequential effect on the Project and/or Study and to make decisions based on experience, skill, and situation, consulting with and/or informing others as appropriate.
- Demonstrated fluency in written and spoken English.

The above description is intended to describe the general nature of the job and may include other duties as assumed or assigned; it is not intended to be all inclusive or limit the duties of the position.

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