Position: Medical and Regulatory Editor

JOB DESCRIPTION:

The person in this position is responsible for conducting quality control (QC) reviews of clinical and regulatory documents, reports, data tables, and slide presentations in support of drug development as well as assisting with the oversight of QC projects assigned to contractors and CROs. In addition, this person is responsible for supporting medical writing activities with supervision.

ESSENTIAL DUTIES & RESPONSIBILITIES:

- Conduct QC reviews of clinical and regulatory documents, reports, data tables, and slide presentations in accordance with predefined, aggressive timelines. A QC review includes comparing all of the data within the tables and text with the source documents to ensure accuracy and ensuring that the messaging is consistent and clear throughout the document and across documents.
- Manage the QC process by serving as the primary contact for QC activities for medical writers, consultants, authors from other functions; and explaining processes, providing support and direction for technical activities, and helping to ensure standard practices.
- Organize complex QC projects and provide guidance to other QC reviewers.
- Support medical writing activities with supervision as needed.
- Lead periodic revision of the Heron Style Guide and help facilitate cross-functional training on the style guide contents and use.
- Complete other tasks as assigned.

REQUIREMENTS:

- Bachelor's or Master's degree in a scientific field.
- Minimum of 2 years' experience conducting QC data reviews and editing. Experience with regulatory documents for the biotech/pharmaceutical industry preferred.
- Expert attention to detail.
- Highly organized and methodical work style.
- Ability to manage multiple projects and adapt to changing priorities for successful project completion.
- Task-oriented view of work with a commitment to timelines and deliverables.
- Excellent proficiency in MS Word with experience adhering to templates and style guides; proficient in other MS Office Suite applications, including Excel and PowerPoint.
- Familiarity with electronic document control and management systems.
- Experience working on regulatory submissions (IND, NDA, MAA, NDS, etc.) in eCTD format preferred.
- Team-oriented with excellent communication and interpersonal skills; demonstrated ability in managing indirectly.
- Ability to work comfortably in a fast-paced and team environment.
- Strong time management skills.

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.

EOE