HERON THERAPEUTICS

Position: Senior Medical Writer

JOB DESCRIPTION:

The Senior Medical Writer in the Medical & Regulatory Communications function is responsible for writing regulatory documents in support of drug development, as well as assisting with the oversight of writing projects assigned to consultants and Contract Research Organizations (CROs). This individual will be responsible for writing and overseeing the production of clinical protocols, protocol amendments, clinical study reports, and Investigator Brochures and for leading or supporting the development of regulatory meeting documents, regulatory responses, and clinical and nonclinical summary documents for regulatory submissions.

ESSENTIAL DUTIES & RESPONSIBILITIES:

- Lead development and writing of clinical and nonclinical regulatory documents and summaries in accordance with predefined, aggressive timelines.
- Assist with overseeing projects assigned to consultants and CROs, including timeline development and management.
- Evaluate draft documents and draft statistical output for accuracy and consistency.
- Represent the function and provide status updates at internal meetings and meetings with external collaborators.
- Support the timely generation of high-quality regulatory documentation by assuming other duties, including document editing, quality control review, and formatting.
- Assist the function head with developing working practices and SOPs.

REQUIREMENTS:

- Bachelors, Masters, or PhD in a scientific or medical field.
- Minimum of 5 years of clinical, nonclinical, and regulatory writing experience in the biotech/pharmaceutical industry.
- Excellent writing skills, with proven ability to accurately analyze, interpret, and summarize clinical and nonclinical data in a clear and succinct manner.
- Experience with producing INDs, BLAs, and NDAs in CTD format.
- Working knowledge of ICH E3, E6, and M4 guidelines and related FDA guidance's on integrated summaries of safety and of efficacy.
- General knowledge of applied clinical medicine and laboratory interpretation.
- Task-oriented view of work with a commitment to timelines and deliverables.
- Ability to manage multiple projects and adapt to changing priorities.
- Strong facilitation, organizational, analytical, and time management skills.
- Team-oriented with excellent communication and interpersonal skills; demonstrated ability in managing indirectly.
- Ability to apply knowledge and experience to new situations.
- Advanced technical competence in MicroSoft (MS) Word, with experience adhering to templates and styles within an electronic document control and management system; overall high proficiency in MS Office applications, including Excel and PowerPoint.

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