



EMPLOYMENT POSTING

Position: Medical Writer
Department: Regulatory Affairs
Status: Direct hire
Reports to: Vice President of Regulatory Affairs & Quality Assurance

Responsibilities:

- Responsible for writing key clinical and regulatory documents, from coordinating the development of strategic messaging through providing guidance on formatting, editing, review and internal approvals, including but not limited to clinical protocols, study reports, investigator brochures, integrated summaries of safety and effectiveness and other clinical regulatory submissions in accordance with ICH guidance with minimal supervision.
- Responsible for managing the process and the preparation, writing, and editing of scientific presentations, preparation of templates, posters, abstracts, and manuscripts with minimal guidance.
- Works in collaboration with, and provides medical writing leadership to multidisciplinary project teams including biostatistics, clinical affairs, regulatory affairs, scientific affairs, manufacturing, quality assurance and legal affairs on a variety of projects with minimal guidance.
- Exercises initiative and utilizes professional judgment to integrate various sources of information into a uniform style with accurate language with minimal supervision.
- Provides leadership and works on problems of diverse scope in which analysis of situations or data requires an evaluation of intangible variables.
- Assumes responsibility for ensuring that the finished document is complete, accurate and complies with the approved format.
- Exercise judgment within defined procedures and practices to determine appropriate action.

Requirements

- Must have 3+ years with the title of Senior Medical Writer or equivalent in a pharmaceutical or biotechnology environment requiring adherence to ICH regulations, with training ideally in the indications of Oncology and Infectious Disease.
- BS/BA degree (minimum) in a biomedical discipline, the candidate will possess previous medical writing experience to demonstrate a clear, concise scientific writing style.
- Must have expert knowledge of the AMA style guidelines; experience with electronic regulatory submissions preferred.
- Demonstrated working knowledge of scientific principles, specifically in the area of oncology and infectious disease.
- Must have an in-depth knowledge of US CFR and ICH Guidelines as well as operational aspects of clinical trials.
- Proficient in the MS Office Suite with expertise in MS Word and prior experience using Visio, Endnote, and Adobe Acrobat.
- Must have hands on experience with regulatory documentation supporting clinical drug development and regulatory submissions from pre-clinical through post-marketing.
- Ability to exercise leadership and work effectively in a fast-paced, dynamic environment.
- Detail oriented, methodical and goal driven.
- Problem solving capabilities and excellent organizational skills.
- Excellent oral, written, and interpersonal skills, as well as the ability to understand and communicate technical, medical, and scientific information.
- Willingness to adapt as work evolves and ability to work in a team environment

Availability: Immediately

Send Resumes To: Human Resources Dept.
SciClone Pharmaceuticals, Inc.
E-mail: humanresources@sciclone.com
Fax: (650) 358-3469
NO CALLS PLEASE