Medical Writer

Remote

Summary

Reporting to Director of Medical Writing, provides technical expertise for Medical Writing activities.

Responsibilities

- Working closely with contributing authors, prepares, reviews and edits documents for organization, clarity, consistency, use of language, and grammar. May contributes to the scientific content if appropriate.
- Assists the lead author in the management of timelines for document preparation, review and approval, including acting as a key liaison with development partners to ensure all stakeholders are aware of their role and accountabilities.
- Incorporates comments into documents produced by key stakeholders, including authors, reviewers, Medical Writing and quality check reviews.
- May provide editorial and peer-review support for other document types (eg, manuscripts or presentations) as needed.
- Proofreads, copyedits, and formats documents to conform with domestic and/or international regulatory submission and internal document standards, while meeting project timelines.
- Participates in study and clinical team meetings and assists teams in resolving issues related to document preparation.
- Optimizes the processes for document review and approval and for document development, including the development and use of templates.
- Stays current on medical writing best practices and regulatory guidelines.
- Expands knowledge/understanding of medical and scientific issues related to document development through professional associations, publications, and/or meetings.
- Other related duties as assigned.

Qualifications and Requirements

- Bachelor's Degree and a minimum of 5 years related experience, or the equivalent combination of education and experience.
- Minimum 3 years of medical writing/editing experience in the biotechnology, pharmaceutical, or medical device industry.
- The ability to quickly understand and assimilate technical and scientific concepts that relate to company publications.
- Experience in preparation of regulatory submissions such as protocols and amendments, informed consent forms, clinical study reports, investigator brochures, development safety update reports.
- Knowledge of GCP guidelines and FDA/other regulatory agency's drug and development requirements as they pertain to the biotechnology/pharmaceutical industry.
- Excellent communication and interpersonal skills in company environment

How to Apply

To apply for this role, please submit your CV and cover letter in PDF format to hr@sierraoncology.com. Please indicate the position title in the subject line of your email.

We thank you in advance for your interest in Sierra. We will contact you directly should we wish to arrange a meeting to discuss this position further.