Trilogy Writing & Consulting is currently looking to hire Senior and Principal Medical Writers to support our growing company in producing regulatory documentation for the international pharmaceutical industry. At Trilogy, you will play a pivotal role in delivering comprehensive services to our clients that extend beyond writing. Our writers are integral members of clinical development teams supporting the writing and coordinating of successful documentation across a broad spectrum of therapeutic areas. As our company continues to expand, there is room to develop with us and your ideas will form our future together. For further insight into who we are and what we do, please explore our website (https://trilogywriting.com).

Trilogy offers the following:

- Competitive base salary
- Annual bonus
- A generous allowance of paid time off (vacation, holiday, birthday, illness).
- Comprehensive benefit plans to include medical, dental, vision, short- and long-term disability, life insurance with AD&D.
- 401K retirement savings plan with company match
- Full AMWA membership and annual conference attendance paid for by Trilogy
- Continuous personal and professional development opportunities
- Free weekly yoga sessions
- Other fun and exciting events to encourage team bonding and development

As a Senior/Principal Medical Writer, you will:

- Prepare a variety of clinical regulatory documents (Clinical Study Protocols, Clinical Study Reports, Clinical Summaries in the CTD format, Investigator Brochures, IMPDs/INDs, scientific publications) as the lead writer in collaboration with members of client authoring teams and supported by other writers, as appropriate.
- Ensure that all documents are produced according to agreed timelines, monitor and manage project budgets, adhere to relevant SOPs, and meet the requirements of Trilogy as well as the company’s clients.
- Be responsible for providing document-specific advice to clients.
- Oversee and coordinate other writers and QC specialists assisting on documents under your responsibility.
- Project manage the timelines and review cycles of your documents.
- Work in the client’s regulatory document management systems.

Candidates must have the following writing experience:

- At least 5 years (Senior Medical Writer) or 10 years (Principal Medical Writer) of experience of actively writing regulatory documents.
- Worked as the lead writer on >3 (Senior Medical Writer) or >5 (Principal Medical Writer) of at least 3 of the following: Clinical Study Protocols, Clinical Study
Reports, Clinical Summaries in the CTD format, Investigator Brochures, IMPDs/INDs, scientific publications.

- For the Principal Medical Writer level, experience in at least 2 different types of CTD dossiers (i.e. full new chemical entity application, a variation, a generic dossier, an orphan drug dossier, a literature-based dossier [e.g. a full-mixed application under Article 8(3) of Directive 2001/83/EC]).
- Experience interacting directly with clients or authors of the documents and coordinating review cycles, meetings, and project timelines.
- For the Principal Medical Writer level, ability and willingness to take on any project for which a Lead Writer is needed.
- Competency in the use of document management systems and review tools.

In addition to having the above writing experience, applicants must have:

- A minimum of a Bachelor’s degree in science/pharmacy (Ph.D. not necessary).
- Fluent written and spoken English skills.
- An appreciation for a well-written document and an eye for details.
- Excellent, proven interpersonal skills, and enjoy proactively participating on a team with diverse personalities.
- Flexibility and the ability to stay focused under tight timelines.
- Must live in the USA or Canada and be willing to work fully remotely or a hybrid schedule (in office/remote) from our Durham, NC, USA office.

To apply:

- Submit an application on our Careers website at: https://trilogywriting.com/jobs/

Trilogy Writing & Consulting is an equal opportunity employer. Our company values are based on inclusivity and diversity, and we do not discriminate or allow discrimination on the basis of race, color, religion, sex, age, sexual orientation, gender identity, national origin, citizenship, marital status, disability, or any other characteristic protected by law. We passionately believe in creating a supportive environment in which everyone can grow, flourish, and do their best work.

It is important to Trilogy to ensure the highest possible degree of protection for your personal data. All personal data collected and processed within the scope of an application for employment with Trilogy are protected against unauthorized access and manipulation by technical and organizational measures and are not forwarded to third parties. Your data will be collected for the purpose of filling employment opportunities offered by Trilogy Writing & Consulting GmbH in Germany or its subsidiaries Trilogy Writing & Consulting Ltd in the UK, and Trilogy Writing & Consulting, Inc. in the USA. By submitting your data with this application, you consent to its use for this purpose within Trilogy. You can revoke this consent at any time without needing to give a reason by informing us of your revocation under jobs@trilogywriting.com. In the event of revocation, we will delete your personal data immediately.