Apellis

Position: Senior Medical Writer

Reports to: Senior Director, Clinical Operations

Description:
Primary objective of the Senior Medical Writer is to provide technical and medical writing support to a variety of regulatory areas including CMC, non-clinical, clinical, and administrative submissions.

Job Responsibilities:

- Work with the clinical and regulatory teams to prepare protocols, protocol amendments, protocol synopses, schematics, study reports, investigator brochures, annual safety reports, and IND/IMPD clinical sections in CTD format under strict timelines.
- Ensure efficient formatting of documents, ensure a consistent style of presentation to maintain quality and ease of review across multiple documents assembled in a regulatory dossier.
- Contribute to overall project management and cross functional working groups as needed to facilitate efficient development and finalization of clinical, nonclinical, and regulatory documents for submissions.
- Assist in the development of the annual medical writing timeline to ensure IB and other pertinent documents are updated as necessary.
- Assist in the writing of overview and other study related manuals (pharmacy manuals, lab manuals, etc.).
- Work with CRO's to ensure study related documents are completed efficiently.
- Participate in the clinical sub-team.
- Other duties and responsibilities as required.

Experience and Background:

- PhD in life sciences or equivalent with a solid understanding of the basic principles of biochemistry and molecular biology.
- 8-10 years experience in a medical writing capacity within the pharmaceutical/biotechnical environment.
- Well organized; able to prioritize tasks, work simultaneously on multiple projects, and complete high quality documents according to tight timelines.
- Working knowledge of biologics development and manufacture, clinical research, study design, biostatistics, regulatory, and medical terminology preferred.
- Detailed knowledge of the requirements for preparation of key clinical, nonclinical, and regulatory documents for INDs, CTAs, BLAs, and annual reports preferred.
- Experience in rare disease and/or ophthalmology preferred.
- Excellent verbal and written communication skills.
- Experience in a start-up environment preferred.
- Must be pro-active team player, flexible, and open to change.