Apellis

Senior Medical Writer - Waltham, Massachusetts

Position Summary:

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.

Key Responsibilities Include:

• 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:

• Advanced degree in a relevant scientific/clinical/regulatory field preferred; Bachelor's degree required.
• 4-6 years' experience in a medical writing capacity within the pharmaceutical/biotechnical environment (or equivalent experience).
• 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.

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Skills, Knowledge & Abilities:

• Well organized; able to prioritize tasks, work simultaneously on multiple projects, and complete high-quality documents according to tight timelines.

Company Background:

We are a clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

Visit http://apellis.com/about.html to learn more.

EEO Statement:
Apellis is an equal opportunity employer and complies with all applicable federal, state and local fair employment practices laws. Apellis strictly prohibits and does not tolerate discrimination against employees, applicants or any other covered persons because of race, color, religion, creed, national origin or ancestry, ethnicity, sex (including pregnancy), gender (including gender nonconformity and status as a transgender or transsexual individual), age, physical or mental disability, citizenship, past, current or prospective service in the uniformed services, genetic information, marital status, AIDS/HIV status, smoker/nonsmoker, and occupational pneumocononiosis or any other characteristic protected under applicable federal, state or local law.