



MEDICAL WRITER POSITION DESCRIPTION

Job Title: Medical Writer
Reports to: Vice President Biometrics or Designee
Classification: Full-time, FLSA Exempt, Salary

Company Summary: Aeglea BioTherapeutics, Inc. is a biopharmaceutical company based in Austin Texas developing novel treatments for inborn errors of metabolism and therapies targeting tumor metabolism. Aeglea BioTherapeutics, Inc was founded in 2013 to develop engineered human enzymes invented in the laboratory of George Georgiou, Ph.D. at The University of Texas at Austin. The Aeglea BioTherapeutics product pipeline consists of a suite of amino acid degrading enzyme treatments. Currently, the company product pipeline consists of the enzymes of AEB1102, AEB3103, AEB2109 and AEB4104. All four are focused on degrading specific targets to treat abnormal human metabolism. Please see www.aegleabio.com for more information.

Position Summary:

The Medical Writer collaborates with members of cross-functional teams to prepare high-quality protocols, investigator brochures, synopses, regulatory documents, clinical publications, and related clinical documents within agreed-upon timelines.

Essential Duties and Responsibilities: To perform this job successfully, an individual must be able to perform the following:

- Prepares, edits, and finalizes protocols, investigator brochures, synopses, regulatory documents and related clinical documents, such as abstracts, posters, presentations, and manuscripts
- Participates in scientific communication planning, including development of strategic medical communication plans
- Partners with the study biostatistician to engage early with the study team including participation in the review of mock and/or blinded tables, figures, and listings (TFLs), and narrative planning for relevant documents
- Works closely with the study team to ensure that results and messages in clinical documents accurately reflect the data in TFLs and other information sources.
- Schedules and conducts document-related meetings including the preparation of pre-meeting agenda, key data points for discussion, and post-meeting minutes
- Collaborates with clinicians, clinical scientists, biostatisticians, and pharmacokineticists to interpret study results and ensure study results and statistical interpretations are accurately and clearly reflected in relevant documents
- Manages the document review process ensuring conflicting and/or ambiguous comments are

clarified and appropriately addressed

- Works closely with the study team to reach consensus on timelines for deliverables
- Completes documents according to agreed-upon timelines and follows up with the study team as needed to meet internal and external timeline commitments, and to ensure SOP and regulatory compliance
- Understands the functions and roles within the study team and aligns with them in delivery of documents to meet project-related goals and to meet external results disclosure obligations
- Manages all aspects of outsourced or internal CSR production and ensures project delivery
- Ensures that medical writing deliverables conform to International Conference on Harmonization (ICH) and other relevant regulatory guidelines
- Creates and maintains standard operating procedures and work instructions for preparation and maintenance of compliant medical writing deliverables
- Ensures documents are generated in accordance with agreed internal processes and standards, are submission ready, and are appropriately stored in agreed document management system
- Ensures that appropriate documented quality control (QC) checks are performed on medical writing deliverables, responds to findings, and recommends quality process improvements
- Suggests or identifies changes, modifications, and improvements to the document preparation processes and templates in order to improve quality, efficiency, and productivity
- Align with department management to set strategy for meeting department goals

Qualifications: To perform this job successfully, an individual must be able to perform each essential duty. The requirements listed below are representative of the experience, knowledge, skill, and/or ability required.

Education/Experience: The ideal candidate will offer:

- At minimum Bachelor degree or equivalent in medical-related field or life science. Post-graduate degree preferred.
- Bachelor's degree +8 years, Master's Degree +5 years, Doctoral Degree +2 years of relevant medical writing experience in the pharmaceutical industry, especially writing in one or more of the oncology or rare diseases therapeutic areas; graduate degree (master's or doctoral) preferred
- An understanding of the drug development process
- Broad experience managing the medical writing responsibilities associated with multiple studies at various stages
- Experience in interacting with cross functional study team members

Knowledge, Skills and Abilities:

- Must have a thorough knowledge of clinical research concepts, practices, and FDA regulations and ICH Guidelines regarding drug development phases, clinical research and medical writing standards; demonstrated ability to interpret and apply these guidelines to document writing
- Ability to work independently with minimal supervision, multi-task, and work effectively under pressure; adapt to change as needed; possess excellent project management skills; attentive to details
- Ability to communicate with teams to set realistic timeline expectations; demonstrated ability to deliver within agreed internal and regulatory timelines; monitor and communicate progress against milestones; escalate complex issues appropriately.
- Excellent interpersonal, active listening, and influencing skills; establishes and maintains professional and productive working relationships with team members

- Ability to utilize a balanced approach to problems, using flexibility and persistence as appropriate
- Read, write and speak fluent English; excellent verbal and written communication skills

Work Environment: This is a high growth, fast paced small organization. The ability to be productive and successful in an intense work environment is critical. Willingness and ability to travel domestically and internationally is required, it is anticipated that this will be less than 10 % of work time.

Physical Demands: The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

The above job description is not intended to be an all-inclusive list of duties and standards of the position. Incumbents will follow any other instructions, and perform any other related duties, as assigned by their supervisor.