Associate Director/Director, Medical Writing

Who We Are

This is an exciting opportunity to join Opus Genetics, a brand new, clinical-stage ophthalmic biopharmaceutical company dedicated to the development of gene therapies for rare inherited retinal diseases. Our approach is based on validated science from pioneers in the ocular gene therapy space. Opus Genetics employs a unique, sustainable manufacturing approach and a commitment to leveraging our clinical network to reach patients and achieve optimal treatment outcomes.

The Role

The Head of Medical Writing will oversee, coordinate, and write for regulatory submissions, manuscript publications, and other medical writing activities within the Opus to achieve company goals and support development strategies. You will partner with the cross-functional teams to develop and maintain integrated writing plans, manage assigned writing activities for regulatory documents and key publications, help maintain program timelines and deliverables, and ensure a timely information flow to and from all relevant authors, reviewers, and stakeholders. Responsibilities will include creating documents pertaining to clinical studies and regulatory submissions, including (but not limited to): protocols, informed consents, investigator brochures, clinical study reports, briefing documents, labeling, clinical summaries for marketing applications, and responses to questions from regulatory authorities.

This role involves close coordination with stakeholders within development (e.g., Clinical Operations, Clinical Development, CMC, Non-Clinical, Regulatory Affairs colleagues within Opus and their collaborators) and outside stakeholders.

Key Deliverables

The highly motivated, goal and results-oriented Head, Medical Writing will:

- Manage the Medical Writing function at Opus and be responsible for the timely completion of all writing projects, including a substantial amount of writing day-to-day. Mentor and train junior medical writing staff as Opus and the development programs grow.
- Create regulatory submission documents that support Opus clinical trials and programs for multiple gene therapy programs in the preclinical, pre-IND, IND/clinical, and commercialization stages.
- Author manuscript publications that support Opus publication goals, in collaboration with Opus team members and external stakeholders.
- Ensure proper assignment of key tasks to team members to complete writing deliverables, including providing team with methods to identify and track quality performance.
- Understand the principles of scientific writing, writing with a variety of audiences in mind, and conveying messages in a clear and concise manner.
- Analyze, interpret, and distill data from multiple data sources to create documents.
- Foster a team culture of ownership, continuous evaluation/improvement; ensure recognition of team achievements and emphasize a culture of openness and psychological safety to ensure high quality, scientifically accurate documents.

- Manage timelines and communications with team, and internal/external stakeholders, to maintain awareness of expectations, milestones, and deliverables for relevant medical writing activities.
- Facilitate effective medical writing and review meetings, setting focused agendas and providing post-meeting documentation (minutes and action items).
- Lead discussions of benefit/risk assessments and team reviews without guidance.
- Support quality control work and provide light formatting assistance for complex documents, as needed.

Skills and Expertise Required

- University/college degree in a relevant field, advanced degree preferred. 5+ years of experience in a biotechnology setting with experience leading the medical writing function.
- Excellent interpersonal, oral, influencing, and written communication skills, as well as an active listener.
- Self-directed and with the ability to be flexible to manage workload. Ability to maintain professional and productive working relationships with team members and external collaborators to achieve timely delivery of high-quality, fit-for-purpose documents.
- Demonstrated leadership and ability to influence across all levels of a cross-functional team without direct managerial relationship.
- Delivers assigned documents on or before deadline, alerting project teams and line management in a timely manner of any anticipated delays, information gaps, or potential shortcomings in quality.
- Ability to communicates Medical Writing's position on resource and timeline needs for assigned documents to project team members, negotiating as needed with the team on these matters and keeping line management informed.
- Strong submissions experience. Comprehensive understanding of the drug development process and how medical writing documents support development at various stages.
- Advanced understanding of medical concepts of the disease and current standard treatments as well as other investigational treatments. Knowledge of how to use publicly available databases (e.g., PubMed, DailyMed, FDA, and EMA sources and guidelines) for literature and information mining to support document content and how to cite such information appropriately.
- Excellent written communication skills and attention to detail related to consistency, grammar, syntax, and accuracy.
- Demonstrated proficiency with word processing, spreadsheet, database, presentation software (MS Office skills such as Outlook, Word, Excel, PowerPoint, and SharePoint) and experience and skill performing medical literature searches.
- Ability to drive decision-making and work with scientific team members at all levels.
- Ophthalmology and/or gene therapy expertise is preferred.
- Ability to work in fast paced emerging gene therapy environment and exemplify Opus Genetics core values of Integrity, Honesty, Transparency, Teamwork, Learning, Urgency, and Diversity & Inclusion.

PLEASE SEND RESUME/CV to careers@opusgtx.com