# Role specification

## Director/Sr. Director Medical Writer

Location: Cambridge, MA

## Position profile:

Provides expertise in medical writing, safety narratives, public disclosure and data transparency requirements and quality standards, partnering with external groups to ensure quality, compliance, and promote innovation in reporting deliverables. Provides the strategic direction and oversight of processes, colleagues and vendors/contractors responsible for the preparation of clinical and regulatory submission documents

- Responsible for (either directly or via oversight) medical writing components of clinical protocols, clinical study reports, summary regulatory documents (eg Investigators Brochure, Annual Report, common technical document (CTD) summaries and overviews) and other associated documents, including primary manuscripts
- Ability to work with relevant team members to ensure clear, consistent interpretation and analysis of complex data and ensure clear, factual, and effective presentation of analyses and associated discussions
- Authority on the interpretation of regulatory guidances related to submission documentation; ensure assigned documents are produced in accordance with relevant internal SOPs and external regulatory guidance
- Drive the document strategies and messages in a collaborative way with relevant lines/team
- Expert in ICH-E3 guidelines, global disclosure regulations, and all applicable standard operating procedures
- Liaise between project team stakeholders and external providers on all aspects of CSR production including disclosure documents for studies assigned to providers, and other clinical documents
- Actively engages and influences functional lines, including clinical, medical, clinical operations, regulatory and other internal groups and external providers
- Provides business line expert system support to ensure document and version control
- Provides advice to external and internal groups on the standards and regulatory requirements for clinical data reporting; including assigning writing resource, as needed
- Suggests or identifies changes, modifications, and improvements to the document preparation processes and templates in order to improve quality, efficiency and productivity; develop innovative options to resolve complex problems
- Potential to work on peer reviewed manuscripts, depending on urgency and work load

## Candidate specification

- PhD with at least 8 years of industry experience, majority in medical writing.

- Medical writing and management expertise with a comprehensive understanding of the drug development and reporting process required for submission document deliverables.
- Track record of communicating complex information and analyses effectively in writing to a variety of scientific and non-scientific audiences.
- Extensive knowledge of vendor processes, contracting, and best practices in outsourcing; ability to influence vendor improvements
- Knowledge of US and EU regulatory/safety regulations and guidelines
- Experience in people management and/or talent development (as growth opportunity in current position)
- Strong organizational skills and ability to prioritize multiple projects and meet deadlines
- Proven accountability and demonstrated strength in interpersonal communication, negotiation, influencing, and problem-solving capabilities
- Ability to work independently with minimal supervision, multi-task and work effectively under pressure; adapt to change as needed; possess excellent project management and issue resolution skills
- Understands the dynamic and requirements of working in a small company
- Proactive nature, with ability to work independently and use initiative
- Strong team player