Director or Senior Director Medical Writing

Reports to: Chief Medical Officer or VP Clinical Development

Classification: Exempt

Summary: Writing clinical study protocols and associated documents, including clinical study reports. Writing regulatory documents (e.g. INCD submission, regulatory authorities briefing documents). Writing scientific clinical documents (e.g. abstracts and presentations, manuscripts). Contribute to corporate communication.

Essential Functions and Job Responsibilities:

- Provide medical writing activities for all clinical studies, from phase 1 to phase 4
- Preparation and production of Investigator's Brochure or DSURs/PSURs
- Develop and produce clinical submission documents for regulatory authorities, US and ex-US (e.g., meetings briefing documents, response documents, CTD summary documents [Module 2.7], Clinical Overview [Module 2.5], and individual study reports [Module 5])
- Facilitate key message and document review meetings and discussions
- Participate in study and clinical team meetings and assist the teams in resolving issues related to document preparation as needed
- Gather and review data to determine the appropriate tabular and textual formats, and the clarity, logic and order of presentation and prepare such data outputs
- Participate in the preparation and production of possible abstracts and/or journal manuscript submissions
- Any other related tasks as may be required by, e.g., review and/or
- Complete other responsibilities as assigned (e.g. corporate communication)

Minimum Qualifications:

- Minimum of BS/BA degree in Science (Masters, PhD or PharmD preferred)
- Minimum of 4-7 years of relevant regulatory writing experience
- Knowledge of FDA, EMA, and ICH guidelines required
- Knowledge of the drug development process, knowledge of rare disease is a plus
- Extensive experience with writing all types of clinical and regulatory documents and with registration dossiers for worldwide use, including experience with summarizing scientific or clinical data
- Experience working with CROs
- Ability to work with complex projects and within cross-functional teams
- Excellent grammatical and communication skills, both written and oral
- Expertise in MS Word, including the ability to solve technical problems with Word templates