

Senior Medical Writer

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Company: George Clinical

Location: bangalore

Category: other-general

We are expanding! We have many new ground-breaking global clinical trial projects in various phases and therapeutic areas across the globe and want your ideas and expertise to help us build and grow. Who are we? A leading global clinical research organization founded in Asia-Pacific driven by scientific expertise and operational excellence 20+ years of experience, ~500 people managing 39+ geographical locations throughout the Asia-Pacific region, USA, and Europe. Full range of clinical trial services to biopharmaceutical, medical device, and diagnostic customers, for all trial phases, registration and post-marketing trial. We combine scientific leadership and global operational excellence, with strong experience in renal medicine, oncology, cardiovascular and chronic diseases across various phases to improve the health of millions worldwide. Why work with us? We are a global team making a difference in the world – our clinical trials improve the health of millions worldwide. Competitive salary and benefits. Flexible and agile working arrangements - onsite, hybrid or WFH (dependent on location). Strong and diverse Learning & Development opportunities including exposure to all aspects of clinical trials with an unparalleled network of Scientific Leaders to learn from. A focus on employee wellbeing including global employee engagement surveys, steps challenges, reward and recognition programs, team building activities and other fun events! About the role: Acts as a Medical Writer on assigned projects. Prepares assigned documents in accordance with George Clinical Standard Operating Procedures (SOPs) and customer requirements and in accordance agreed timelines. May provide feedback to peers when asked for input or review. Negotiates timelines and discusses/resolves customer comments. Keeps abreast of current medical and/or technical writing/regulatory knowledge,

including GCP, along with developments and advances in drug development/medical and/or technical writing. Key Accountabilities: Take a leading role in preparing assigned documents, including, but not limited to, confirming the scope of the task, confirming templates and specifications, negotiating, and adhering to timelines, organizing document reviews, communicating directly with the customer. Manage day-to-day workload: identify project needs, track timelines, and implement customer requests, keeping manager/senior staff abreast of progress on tasks and any potential problems with project work. May take the role of Project Manager for a small and short Medical Writing project as required. Display excellent technical accuracy, correct interpretation of source documents, a high focus on attention to detail, with adherence to timelines and budgeted hours. Methodically incorporate internal/customer comments using a scientifically accurate and balanced approach and, with minimal management support and oversight. Possess excellent interpersonal/communication skills to enable effective and professional liaison with internal team members, customers, and other key stakeholders. Develop Standard Operating Procedures (SOPs) and Work Instructions (WIs) relating to medical writing services as appropriate. Develop systems to support the delivery of medical writing activities. Proactively contribute creative ideas, concepts, or suggestions to provide added value on assigned activities. Complete and document mandatory training for this role within specified timelines. Comply with all applicable regulations, guidelines, SOPs, and project-specific requirements. Provide input to systems, tools, and process improvements. Oversee onboarding training for newly appointed medical writing personnel. Work with Director, Medical Services on business development activities relating to medical writing, make assessment on the scope of work and completion timeline. Support Director, Medical Services on overseeing George Clinical's Medical Writing projects to ensure quality output delivery and compliance to study timeline and pre-defined scope of work. Skills, Knowledge and Experience: A minimum of bachelor's degree in life sciences related discipline or related field. At least 5 years of medical writing experience in writing clinical trial protocols, investigator brochures and clinical study reports. Good awareness of current industry code of practice guidelines and their implications. Familiarity with the structural and content requirements of clinical study reports, protocols, and similar documents. Ability to identify deficiencies, errors, and inconsistencies in a protocol or report. Ability to integrate, interpret, and summarize data from a variety of sources in a clear and concise manner. Working knowledge of drug development, medical writing, and associated regulations. Good understanding of statistical principles and of medical terminology across a

range of therapeutic areas. Excellent written and oral communication skills including grammatical/technical writing skills. Excellent attention to detail and accuracy. Communicates clearly, effectively, and confidently with others. Ability to establish and maintain effective working relationships and collaboration with co-workers, managers, and customers. Ability to work both independently and in a team environment. Ability to perform multiple tasks and prioritise work effectively. Strong computer skills, including MS office, Word, PowerPoint, Excel, Outlook, and Internet. Budgetary awareness. Presentation skills. We are searching for individuals who are excited by the idea of regional and global projects and teams, don't want to get lost in a large CRO and are ready to have their ideas heard! You will be willing to extend yourself and take on new challenges while living our values of Mutuality, Integrity, Can-do approach, Empowerment and Excellence. How do I apply and what if I'm interested in a role in future or want to refer someone? Apply via LinkedIn or send your CV, referral or confidential query to careers@georgeclinical.com and our friendly HR team across the world will reach out as appropriate soon. Please provide your full contact details, the location you are applying for, whether you are interested in a current or future opportunity and we'll be in touch. We are reviewing applications as we receive them but please note that only short-listed applicants will be contacted. How do I learn more about the roles and George Clinical? Follow us on LinkedIn to see our regular updates and how we celebrate our people and success across our business and projects! You can also visit us at www.georgeclinical.com. We are reviewing applications as we receive them but please note that only short-listed applicants will be contacted. Thank you for your interest in working with George Clinical. As a global business, we are committed to handling Personal Information in accordance with applicable privacy and data protection laws in the many countries in which we do business. Please see our Privacy Policy for further information. <https://www.georgeclinical.com/privacy-policy-statement>

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