



Senior Medical Writer

Belgium, Denmark, France, Germany, Portugal, Romania, Spain, Sweden, United Kingdom

Reference Number:

The Aixial Group is an International Contract Research Organization (CRO), a member of the ALTEN Group, with offices located in France, UK, US, Belgium, Denmark, Sweden, Switzerland, Romania, and India.

The CRO occupies a unique position in the clinical research industry, supporting biotech in clinical trials across all phases (Ph. I - IV) and non-interventional studies, as an expert in the operational delivery of clinical trials. Our vision is to conduct clinical trials better than anyone else, to help patients and ultimately save lives. We have earned a strong reputation for successfully delivering complex, demanding and innovative clinical trials.

We are currently looking for an enthusiastic and talented Senior Medical Writer for a client dedicated opportunity. This role is home-based in the UK or EU, or office-based/hybrid in Denmark and Sweden.

The successful candidate will be overall responsibility for coordinating and managing medical writing tasks, including timely delivery of high-quality documents in accordance with agreements made between Aixial and sponsor. Key medical writing tasks include clinical study reports, Investigator's Brochure (IB) updates, protocols, as well as summary documents and clinical overviews for submission to regulatory authorities. The candidate will be expected to work in alignment with company values and in compliance with ICH-GCP, national and international regulations and the client's quality system. They must provide timely feedback to management on work progress and actively participate in scheduled training sessions and required reading. Other medical writing tasks may be assigned as needed. Aixial offers a friendly and stimulating work environment, with ample opportunities for professional growth.

Qualifications

- Advanced degree in life science
- Preferably 5 - 10 years of relevant medical writing experience
- Ability to structure and plan own work according to agreed timelines

- Excellent attention to detail combined with an understanding of the document's overall purpose
- Ability to work simultaneously on more than one project
- Ability to establish and maintain effective working relationships with co-workers, managers and clients
- Knowledge of GCP as well as relevant ICH guidelines

Technical skills

Good knowledge of Microsoft Office 365. Experience with Veeva and PleaseReview is a plus.

Languages

The job holder will need to be fluent in spoken and written English.

For more information on Aixial Group recruitment and consideration for other opportunities, please

review the recruitment statement on our careers page - <https://www.aixialgroup.com/join-us/>

Please be aware that we do not accept resumes from outside agencies or recruiters unless specifically requested by Aixial Group Talent Acquisition. Unsolicited agency or recruiter resumes will not be eligible for referral fees and will be considered candidates Aixial may directly contact for employment application.

Your contact person