

## Job Opening **Senior Medical Writer**

ICRC-Weyer is an expert life science consultancy based in Berlin, with over 30 years of experience supporting companies in the pharmaceutical, biotech, and medical device sectors. Our team provides scientific and technical expertise across the entire product life cycle – from pre-clinical development to post-marketing. We offer a wide range of services, including high-level consulting, regulatory oversight, document development, and contract research services.

At ICRC-Weyer, we pride ourselves on delivering tailored solutions that help our clients navigate complex regulatory landscapes and bring innovative healthcare products to market. Joining our team means working in a dynamic and collaborative environment where expertise, innovation, and quality drive everything we do.

### **Your responsibilities**

- Prepare a variety of documents for global submission across all phases of clinical development and post-marketing, covering multiple therapeutic areas. Documents include clinical study protocols/reports, clinical overview/summaries, Investigator's Brochures as well as aggregate safety reports and Risk Management Plans
- Collaborate with cross-functional teams, including pharmacovigilance, regulatory affairs, and clinical development
- Review complex documents to assure consistency, accuracy, and alignment with client standard and regulatory requirements (e.g., ICH, GVP, and MDR)
- Manage review cycles and project timelines together with clients and internal teams
- Serve as a subject matter expert for clients on medical writing and regulatory documentation
- Mentor, train, and provide guidance to junior writers

### **Your qualifications**

- A minimum of 5 years of experience as a Medical Writer in the contract research, biopharmaceutical, or medical device industries
- Proven expertise in preparing at least three types of clinical, regulatory, or safety documents (e.g., study-related, submission-related, or safety-related). Experience with both pharmaceuticals and medical devices is a plus
- Strong knowledge of drug development process and key regulatory requirements (ICH and GVP guidelines). Familiarity with medical device guidelines (MDR 2017/745, ISO 14155, MDCG)
- Understanding of key therapeutic areas in clinical development within the biopharmaceutical and medical device industries
- Ability to interpret and summarize complex clinical/safety data with clarity and precision
- Proficiency in literature database searches and referencing software
- Strong MS Word skills (Word 365) and willingness to work with document management systems and collaboration platforms
- A proactive mindset, intellectual curiosity, and willingness to expand expertise into new fields

### **Our offer**

- Fully remote work or hybrid-remote with team collaboration days in our Berlin office
- A supportive, diverse, and engaged team with flat hierarchies
- A permanent contract with a competitive salary and an attractive benefit package
- Active participation in professional development programs, including EMWA membership

Please send your application, incl. desired salary, to [jobs@icrc-weyer.com](mailto:jobs@icrc-weyer.com).