

Independent Clinical Research Consulting

## About us

ICRC-Weyer is an owner-managed contract research organisation and consulting firm with over 25 years of history, based in Berlin. To our clients from the international pharmaceutical and medical device sectors, we offer functional and consulting services, covering the product life cycle from clinical development to post-marketing. Medical writing, pharmacovigilance, biostatistics, and data management are among the core services of our portfolio. The satisfaction of our clients and the well-being of our employees are our top priority and the key to our success. You are invited to be a part of that! We are currently looking for:

# Drug Safety Scientist / Senior Safety Writer (f/m/x)

# home- and/or office-based in Berlin

# Your responsibilities

- Writing, compilation and editing of pharmacovigilance / device vigilance documents including documents for regulatory submission during all phases of clinical development and the post-marketing period, such as case narratives, risk management plans, periodic benefit-risk evaluation reports, periodic / development safety update reports and investigator's brochures
- Detail-oriented review of complex documents, assurance of consistency within and across documents
- Analyse and process reports, line listings and summary tabulations from safety databases
- Perform signal detection and evaluation activities
- Safety review of clinical data, including case report forms and laboratory outputs
- Project management, incl. client communication and organization of internal project teams
- Training, mentoring and supervision of Safety Writers

## **Your qualifications**

- At least 5 years of experience as a Safety Scientist / Safety Writer in the contract research or biopharmaceutical industries
- Excellent understanding of drug development processes, pharmacovigilance processes, and key regulatory requirements (e.g., GVP modules, ICH guidelines)
- Excellent English language skills
- Proficiency in literature database searches
- Proficiency in one or more safety databases
- Proficiency in MS Word (Word 365) and Endnote literature referencing software, proficiency with PerfectIt editing software is considered a plus
- MD, or PhD in a relevant discipline
- Curiosity and willingness to acquire expertise in new fields

## Our offer

- A friendly, diverse, and committed team with flat hierarchies
- Opportunities for professional development and a high degree of personal responsibility
- A permanent contract with a competitive salary and an attractive retirement package

Please send your application, incl. desired salary, to jobs@icrc-weyer.com. We look forward to hearing from you!

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