Senior Medical Writer | Regulatory Documents

FIRSTNAME LASTNAME

Berlin, Germany (remote) | firstname.lastname@email.com
linkedin.com/in/yourname

Profile

Medical Writer with seven years of experience, five of them in regulatory writing at a CRO. Writes clinical study protocols, clinical study reports, investigator's brochures and Module 2 summaries for submissions to the EMA and FDA. Life sciences doctorate. Manages review cycles with cross-functional teams across time zones.

Career highlights

- Wrote or co-wrote more than 40 clinical study reports and 15 protocols.
- Lead writer for the clinical overview and summary of clinical safety in a marketing authorisation application.
- Cut CSR review cycles from four to three rounds with a shared template and comment-resolution process.
- Trained six junior writers on ICH E3 and the company style guide.

Professional experience

Senior Medical Writer **August 2021 to present**
Global CRO (example) Remote, Germany

- Write protocols, CSRs and investigator's brochures to ICH E3 and E6.
- Draft Module 2.5 and 2.7 documents for submissions.
- Lead review meetings and resolve comments with clinicians, statisticians and regulatory.

Medical Writer **March 2019 to July 2021**
Medical communications agency (example) Berlin, Germany

- Wrote manuscripts, congress posters and slide decks for pharmaceutical clients.
- Checked claims against references and compliance codes.
- Coordinated author reviews.

Education

Charité, Berlin. Doctorate (Dr. rer. medic.) in medical neurosciences, 2018 | Master of Science in Molecular Medicine, 2014

Further training

EMWA professional development programme, regulatory writing modules (2022) | Plain language summaries (2024)

Languages

German (native) | English (near-native)

Core competencies

Regulatory writing | Clinical study reports | Protocols | Investigator's brochures | CTD Module 2 | ICH E3 and E6 | Review management | Publications | Plain language summaries | AMA style

Sample CV with invented content. Free Medical Writer CV template by Andreas Schulz, MoreThanCareer.de:
morethancareer.de/cv-templates/medical-writer-cv-template.html