CONSULTANT CLINICAL AFFAIRS (M/F/X)

Location: Germany-Nürnberg (remote, hybrid or office-based), Employment Type: Full-time, flexible working hours possible

RESPONSIBILITIES:

- Provide and update documentation in the field of Clinical Affairs for medical devices (e.g. clinicalevaluation, post-market clinical follow-up and post-marketing surveillance)
- Contribute to planning, authoring, updating, and maintaining clinical evaluation plans/reports as well as of PMS plans/reports/ PSURs, PMCF plans/reports, and SSCPs in compliance with EU MDR 2017/745, IVDR 2017/746, MEDDEV 2.7/1 Rev 4
- Conducting systematic literature reviews
- Conduct reviews of CER and PMS documentation to ensure data integrity, accuracy, and compliance with procedures
- Close cooperation with other medical writers, and with other departments both within the company and on the client's side
- Managing daily activities to ensure timelines are met

QUALIFICATIONS:

- You have a Masters' degree, preferably in a science related field (medical engineering or medicine preferred), advanced degree is highly desired
- You have a minimum of 1-3 years of Clinical/Technical Writing experience in a highly regulated industry
- You have in-depth knowledge of international regulatory standards related to CER and PMS (e.g., MEDDEV 2.7/1 Rev 4, EU MDR, EU IVDR, MDCG documents)
- You have scientific/medical writing skills
- You have experience in literature research
- You have a goal-oriented and analytical way of thinking
- You can adapt fast and keep a cool head even in stressful times
- You are strong, working independent, as well as collaborative within a team
- You are fluent in written and spoken English, German proficiency is preferable
- You have excellent communication and interpersonal skills

TO APPLY, PLEASE SUBMIT YOUR RESUME AND COVER LETTER TO [JOBS(AT)BE-ON-QUALITY.COM].