THIS JOB OFFER MAY BE FORWARDED TO INTERESTED CANDIDATES!

MONIPOL

As a Clinical Research Organization (CRO) we are supporting our clients with the regulatory approval for new medicines, new biotech solutions, and new medical devices. We are currently in the process of a Digital Transformation. Hence, we are a "start-up" with 30 years of experience!

JOIN OUR TEAM! – As of now in Bonn (DE) we are looking for (fulltime)

Regulatory Affairs Specialist (m/f/d)

What We Offer You

- ✓ Being recognized as the expert you are
- ✓ Well-established clinical research organization with proven procedures and good reputation
- ✓ Reliable and stable company that provides support and backup when needed
- ✓ Startup culture open for innovation and your personal ideas for optimization
- ✓ Full time preferred, but other arrangements like freelancer or part time possible
- ✓ Home office possible, but on-site presence is occasionally required
- ✓ Many opportunities to further deepen your specialist knowledge to advance your career
- ✓ Interesting challenges and team support that helps you to grow both, personally and as an expert

Your Tasks With Us

- ✓ Completion, tracking and archiving of reports, documents and information required for authorization
- ✓ Obtaining all documents and information necessary to conduct the trials
- ✓ Setup and management of trial master file (TMF) and investigator site file (ISF)
- ✓ Ensuring regulatory compliance of all our activities and procedures
- ✓ Updating information on regulatory requirements related to our trials and processes
- ✓ Regular reporting on study status
- ✓ Correspondence with sponsors of the trials, research sites, authorities and investigators
- ✓ Preparing submission packages for ethics committees and regulatory authorities

Your Profile

- ✓ Being obsessed with details is something positive for you
- ✓ You are very precise and meticulous and you strive for order and perfection
- ✓ You like to analyze and assess complex information to form judgements and make decisions
- ✓ You have excellent organizational skills, the ability to work under tight deadlines and to prioritize tasks
- ✓ Knowledge of clinical trial conduct is required; knowledge of medical law is not required but preferred
- ✓ Ideally you already gained work experience as regulatory affairs specialist or with regulatory authorities or in clinical research but this is not a necessity
- ✓ You hold a degree in clinical research, science, medicine or other related areas
- ✓ Required are both, good German and good English language skills (B2 or better)

Sounds Interesting? Apply Now!

Online: https://join.MONIPOL.com/apply

By Email: career@MONIPOL.com

Additional information & further job offers:
https://join.MONIPOL.com

Any Questions?

If you have any questions, feel free to contact us:

Dr. Moritz John
career@MONIPOL.com