



Mainz Biomed is an international, innovative, and emerging biotechnology company. It specializes in the development of in vitro diagnostics in the field of cancer prevention and targets laboratories, physicians, companies, and patients with its portfolio.

To support our team, we are looking for a

## **Clinical Trial Manager (m/w/\*)**

as a fulltime employee (40h/week), home office based located in the USA.  
Reporting line to the Vice President of Clinical Affairs.

### **Your responsibilities:**

- Successfully manage any assigned studies ensuring completion of the deliverables.
- Create, review, and/or oversee study documentation such as protocols, case report forms, monitoring plans, data management plans, statistical analysis plans, etc.
- Lead the development of study tools and training materials.
- Organize, oversee, or perform study operational elements such as site feasibility, qualification, selection, initiation, monitoring, for-cause site visits, and close out.
- Oversee study laboratory investigational product management, sample management and sample testing.
- Participate in oversight of any CROs or vendors engaged by Mainz Biomed.
- Assist with site engagement and support.
- Lead team study meetings.
- Communicate any challenges to study timelines and deliverables and help with creative solutions.
- Create and/or edit department SOPs and other procedures.
- Mentor and train junior department members.
- Up to 50% travel may be required.

### **Your profile:**

- Bachelor's degree or combined equivalent education and experience in a science or health-related field.
- At least 5 years clinical research experience on IVD clinical studies (7 years for Sr. Clinical Trial Manager).
- Independent field monitoring experience.
- Experience with EDC and eTMF systems.
- Extensive knowledge of US 21 CFR, GCP and ICH Regulations.
- Clinical research certification (e.g. CCRA or CCRP) desired.
- Study experience in a leadership role desired.
- Excellent organizational and time management skills.
- Excellent verbal and written communication skills.
- Ability to work with and lead a multifunctional team.
- Skills in negotiation, building positive interpersonal relationships, critical thinking, flexible thinking, and making decisions.
- Advanced knowledge of MS Office products.

**We offer:**

- A wide range of activities
- Attractive compensation including stock options
- Flexible working hours and work location
- Flat hierarchical structures
- The chance to contribute to an innovative and highly motivated team

Are you interested? Then please send your application documents, your salary requirements, and your earliest possible starting date by e-mail to [jobs@mainzbiomed.com](mailto:jobs@mainzbiomed.com). Your contact person, Jane Edwards will be happy to answer your questions in advance via this e-mail address.