Clinical Project Manager (experienced)

The European Vaccine Initiative (EVI) is a non-profit organisation that is dedicated to accelerating the development of vaccines for diseases of poverty and emerging infectious diseases.

We work with academic partners, pharmaceutical companies, public health institutes, WHO, the European Commission and many other like-minded organisations across the world to discover and develop safe, effective, and affordable vaccines.

EVI has an exciting full time career opportunity for a motivated individual to join the organisation as

Clinical Project Manager (experienced)

You will join an enthusiastic non-profit organisation that includes a diverse, international team of about 17 staff, comprising scientists, vaccinologists, experts in clinical trials and regulatory matters, project managers and office support staff.

As clinical project manager you will work with internal colleagues and external partners on vaccine development and evaluation at all stages, but particularly in early clinical phases. The successful candidate is expected to support the progress of international collaborative clinical trial projects and to ensure that the clinical trials are conducted, recorded, and reported in accordance with protocols, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and applicable regulatory requirement(s)

Responsibilities:

- To assist in the coordination and execution of clinical trial projects
- To ensure absolute adherence to Good Clinical Practice (GCP) in accordance with ICH-GCP standards, Declaration of Helsinki, regulatory requirements, and study procedures
- To develop/update SOPs in accordance with ICH-GCP standards, Declaration of Helsinki and regulatory requirements
- To develop, review and edit clinical trial related documentation including but not limited to : protocols, CRFs, Informed Consent Forms, study specific SOP, monitoring plans/ reports and clinical study reports
- To complete and compile all necessary research, documentation and information to gain appropriate regulatory and ethical committee approval where required
- To assist in scientific advice requests to regulatory agencies
- To interact with and manage vendors and stakeholders, as required
- To assist in project management and reporting activities
- To facilitate effective implementation of project activities, in particular the delivery of projects to agreed timelines and budget
- To report and present to core teams and upper management
- To highlight and present any difficult issues that need the attention of upper management
- To organise teleconferences, meetings, and workshops.

Visit our website (www.euvaccine.eu) to learn more about us and what we do.

Qualifications/Essential Skills/Competencies:

- Masters, MD or PhD in a relevant scientific discipline
- **Minimum 3 years' experience in investigational clinical research in a pharma company or CRO or in a regulatory agency**
- Proven track record of training and adherence to ICH-GCP
- Knowledge of the EU regulatory requirements for investigational clinical trials
- Ability to contribute to the development of clinical trial related documents and materials
- Clear understanding of the vaccine/drug development process
- Excellent presentation skills including the ability to meet exacting standards and a keen attention to detail
- Ability to work independently (and remotely), yet still in a team.
- Willingness and ability to travel
- Fluent in written and spoken English.
- Knowledge of Microsoft Project and Microsoft Office is mandatory

Desired Skills/Competencies:

- Experience in clinical research quality management
- Planning and organising: Proven ability to be able to plan and manage clinical trials.
- Ability to work within deadlines
- Ability to work in multicultural environment and to maintain effective working relations with people of different nationalities and cultural backgrounds

Conditions of Appointment

- Contract period will start as soon as mutually agreeable.
- Our headquarters are situated in Heidelberg (Germany) and always welcome staff to use our offices - but staff can work remotely from home following an initial inception period lasting 3 months while being trained for the job.
- We manage payroll in Germany, Denmark and Belgium and can easily accommodate staff anywhere in those countries by remote home working options.
- The position is initially limited to three years but is technically an option for permanent placement.

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Applications with the requested information should be submitted in **English!**

Applications must contain a **CV and a Motivation letter** - in the motivation letter please explain why you are applying to EVI and why you think you are qualified for the position.

Applications must be Received no later than **18th July 2022**

Please send your application by email to; sten.larsen@euvaccine.eu

Insert **"Clinical Project Manager application"** in the subject line.

We reserve the right to close the application process earlier in case a suitable candidate is identified - so please forward your application as soon as possible.

Thank you for your kind interest thus far!