European Vaccine Initiative

www.euvaccine.eu
+49 6221 565373
contact.us@euvaccine.eu

UniversitätsKlinikum Heidelberg
Voßstraße 2, Geb. 4040
69115 Heidelberg, Germany

Clinical Project Manager

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 career opportunity for a motivated individual to join the organisation as

Clinical Project Manager (Full Time, Germany)

You will join a young, enthusiastic non-profit organisation that includes a diverse, international team of about 20 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.

Qualifications/Essential Skills/Competencies:

- Masters, MD or PhD in a relevant scientific discipline (*e.g.*, clinical research, vaccine development, immunology, molecular biology, pharmacology, biological sciences).

European Vaccine Initiative

www.euvaccine.eu
+49 6221 565373
contact.us@euvaccine.eu

UniversitätsKlinikum Heidelberg
Voßstraße 2, Geb. 4040
69115 Heidelberg, Germany

- Clear understanding of the vaccine/drug development process
- Experience in clinical research and product development
- Proven track record of training and adherence to ICH-GCP and applicable local regulatory requirements during the conduct of clinical trials
- Ability to contribute to the development of clinical trial related documents and materials
- Good communication skills including the ability to present complex information to both clinical and non-clinical disciplines
- Excellent presentation skills including the ability to meet exacting standards and a keen attention to detail
- Ability to prioritize, and the ability to work in a multi-task environment.
- Ability to work independently (and remotely), yet still in a team.
- Ability to deliver high-quality results against deadlines.
- Willingness and ability to travel
- Fluent in written and spoken English.
- Knowledge of Microsoft Project and Microsoft Office is mandatory

Desired Skills/Competencies:

- Experience across a wide range of clinical indications / therapeutic areas
- Experience in a pharma company or CRO or in a regulatory agency is a plus
- 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:

- The candidate must have, in advance, an obligatory German or EU work permit!
- Contract period will start as soon as mutually agreeable.
- Our headquarters are situated in Heidelberg (Germany) but staff can work remotely following an initial inception period.

If you feel that you possess the relevant skills, please send a Curriculum Vitae and cover letter explaining your suitability for the position and your salary expectations.
Visit our website (www.euvaccine.eu) to learn more about us and what we do.

Applications with the requested information should be submitted in English and received no later than **3 January 2022**. However, we reserve the right to close the application process earlier in case a suitable candidate is identified.

Applications or any questions related to the position should be sent by email to:
Sten Larsen Finnsson
Human Resources Director
sten.larsen@euvaccine.eu