European Vaccine Initiative

www.euvaccine.eu
+49 6221 565373
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UniversitätsKlinikum Heidelberg
Voßstraße 2, Geb. 4040
69115 Heidelberg, Germany

Quality Assurance Manager

(part-time or full-time, Heidelberg/Germany or remote)

You will join a young, enthusiastic non-profit organisation with a diverse, international team of about 25 members, including scientists, vaccinologists, experts in clinical trials and regulatory matters, project managers, and office support staff.

The European Vaccine Initiative (EVI) e.V. 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, and many other like-minded organisations across the world to discover and develop safe, effective, and affordable vaccines for people in low- and middle-income countries.

EVI offers you flexible work arrangement, a purposeful mission towards solving major global health challenges and the possibility to learn from our science-driven experts. We are headquartered in Heidelberg, Germany, but we offer the possibility to work remotely from other locations in Europe.

Responsibilities:

1. Quality Assurance

- Review trial/study documents to ensure compliance with Standard Operating Procedure (SOPs), regulatory requirements, and best practices.
- Perform consistency and quality control checks.
- Ensure the quality of all trial/study documents archived.

2. Risk assessment

- Develop and implement a risk-based approach to quality assurance within EVI.
- Write and review risk assessment for clinical trials and monitoring plan during the life cycle of a trial.
- Ensure that risk-based monitoring plans are being followed and are effective and reviewed periodically.

3. Standard Operating Procedures (SOPs)

- Take overall responsibility for initiation/preparation, review, update and implementation of the clinical trial SOPs to ensure continuing compliance with SOPs, policies, national and European Union (EU) regulations.
- Assist with the maintenance and evolution of EVI's document management system for SOPs, including drafts, active, and superseded versions.
- Be responsible for tracking the status of all SOPs.

4. Compliance and audits

- Undertake proactive audits of both systems and trials, including preparation of audit plans, audit reports, and tracking from plan to close.

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- Identify areas of non-compliance and prompt corrective actions and follow-ups when appropriate.
- Prepare for, conduct and follow-up on internal, vendor and site audits.
- Lead the preparation of staff and trial materials for audits by internal and external bodies, supporting staff during audit and with any follow-up actions -Corrective Action and Preventive Actions (CAPAs)-.

5. Regulatory Inspections

- Take responsibility for preparing trial materials for inspections by the European Medicines Agency (EMA) or other regulatory bodies, supporting staff during inspection and with any follow-up actions (CAPAS).

6. Communication

- Work closely with EVI's clinical trials and research teams.
- Be proactive in forming links with quality assurance (QA) staff working within other national European and international institutions as required.
- Develop excellent working relationships with the clinical trial team members within EVI and partner institutions.

7. Training & Development

- Ensure that trials staff, including Investigators and Coordinators, are familiar with, understand and are implementing the relevant SOPs.
- Work with the EVI Executive Director and Director of Vaccine Development to enhance the training programme delivered to staff.
- Work with relevant colleagues to design and deliver specific training as demand arises.
- Be proactive in closely monitoring changes to regulations and relevant guidance to the conduct of clinical research including clinical trial regulations, Good Clinical Practice (GCP) guidance, data protection regulations, ethical guidance and safety reporting.

Essential Skills/Competencies:

- University education in technical or bioscience.
- Clinical research experience including protocol development and implementation.
- Good experience of conducting, managing, auditing or monitoring in a Good Clinical Practice (GCP) environment.
- Solid knowledge of the EU regulatory requirements for investigational clinical trials, Guidelines for GCP, General Data Protection Regulation (GDPR) and the ability to interpret these in a non-commercial environment.
- Ability to work constructively as an individual, as part of a close-knit team, and as part of large collaborative project.
- Flexible and adaptive approach to work. An organised approach to dealing with large numbers of complex documents and the ability to think on one's feet under pressure.
- Excellent communication, persuasion, listening and strong interpersonal skills as well as attention to detail and a sharp analytical mind and an ability to think laterally.

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- Excellent IT literacy: evidence of competence with MS Office, particularly Excel, Word, PowerPoint and Access.
- Ability to teach and mentor.

Desirable selection criteria

- Experience of working in an academic, non-profit or in a healthcare-related industry.
- Experience of working in collaborative projects, involving cooperation with partners in sub-Saharan Africa.
- Experience of working on clinical trial or non-interventional study.
- Hands-on knowledge of applicable regulations and guidelines.

EVI offers you:

- Flexible working hours, employee benefits, career development opportunities.
- Partly or fully home office if compatible with the tasks
- 30 vacation days based on a 5-day workweek, 2 child-care days per child of up to 12 years.

Additional application conditions:

- Applications with the requested information should be submitted in English.
- **Please send your application (or questions) by email to: Marielle Boslet, HR Manager, marielle.boslet@euvaccine.eu and kindly insert "Quality Assurance Manager Application" in the subject line.**
- Applications must contain a CV and a Motivation letter - in the letter please explain why you are applying to EVI and why you think you are qualified for the position. Kindly include your salary expectations.

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

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

Thank you for your interest in working with us!