www.kiro.bio

QARA Specialist
CDI

Apply: jobs@kiro.bio

Location: Paris
Starting date: May 2024
Requirement: Master's degree (or equivalent) and 3+ years' experience

🚀 KIRO'S MISSION

Founded in 2019, Kiro is the first AI-powered digital health platform for clinical biology in Europe, leveraging lab results to bring better outcomes for patients, and information support to physicians and life science companies.

Kiro brings novel insights by standardizing and analyzing laboratory test results to drive an increased understanding of disease and outcomes.

Thanks to real-time recommendations and clinical decision support tools (prevention, treatment and diagnosis) leveraged by artificial intelligence, Kiro's solutions, already used by millions of users, allow patients from leading laboratories, hospitals and providers to better monitor their health, doctors to make better decisions, and to consider the treatment best suited to each patient's biological profile.

Kiro has raised more than 15m$ and a series A led by world class reknonwn investors.

✨ YOUR ROLE & RESPONSIBILITIES

To support our growth, we are looking for a highly motivated QARA Specialist to join our team. As medical devices, our AI solutions need to go through a thorough compliance and certification process. As a QARA Specialist you will oversee all aspects of the QMS and product regulatory compliance.
Your role and responsibilities will be:

Quality Management

- Develop and maintain the Quality Management System to ensure compliance with applicable regulations. Participate in Kiro's QMS continuous improvement and monitor Quality KPI
- Manage NC, CAPA & Complaint process: Drive and collaborate with cross functional team members to develop action plans and adhere to process phase timelines
- Manage Quality Post-market activities: Monitor product performance, providing data to support decisions regarding the safety and effectiveness of the product
- Participate in internal and external regulatory audits

- Provide regular training to the team and foster a culture of compliance and continuous learning within the company
- Manage Product change control process to ensure product compliance throughout their life-cycle: guarantee that regulatory requirements are met and manage technical documentation necessary for product release

Regulatory Affairs:

- Prepare and submit regulatory documentation to obtain and maintain product approvals and certifications
- Manage relationships with notified body and regulatory authorities
- Perform regulatory and standard watch
- Provide regulatory support to sales and marketing (promotion & communication)
- Participate to the design and evaluation of clinical activities

🦸 OUR NEXT TEAMMATE

Some of the main characteristics we're looking for:

- Master's degree in engineering, biomedical sciences, or in the field of Regulatory Affairs or Quality assurance
- Strong knowledge of regulations and standards related to medical device such as (UE)2017/745 MD regulation, QMS standard & regulations (ISO 13485, 21 CFR), and product related standards such as ISO 14971, IEC 62366, IEC 62304 and IEC 82304-1
- You can work autonomously with strong analytical and problem-solving skills and with meticulous attention to detail
- Ability to work collaboratively in cross-functional teams with a great team spirit
- You adapt quickly to new environments and challenges, are willing to take initiatives and strive to continuously improve yourself
- Strong French and English language skills

🏝️ WORKING ENVIRONMENT & ADVANTAGES

By joining Kiro, you will have the opportunity to:

- Work in a dynamic and ambitious start-up on a mission to transform healthcare 🙌
- Join a recognized, multi award-winning start-up, in a critical role 🌟
- Be part of a diverse team that likes nothing more that working hard and playing hard together 🤝
- Icing on the cake: Have an attractive package, Alan Health, Swile lunch card and much more 🎉

Do you have what it takes?

Send your CV at jobs@kiro.bio

More information about us on www.kiro.bio