Ava is a digital health company with offices in Zurich, San Francisco, Belgrade and Makati that aims to advance women's reproductive health by bringing together artificial intelligence and clinical research. Our wearable device, smart app and proprietary predictive algorithms empower women by giving them unique clinically researched insights and personalized data about their menstrual cycle, fertile window, and pregnancy delivered in a way that's convenient and non-invasive. Ava was voted Best of Baby Tech at CES 2017, named a Women's Health "Editors' Choice" product and has been honoured as the best Swiss startup in 2017 and 2018. Our current key markets include USA, Germany, Switzerland and UK.

Would you like to join us on our challenging adventure? To strengthen our team, we are looking for:

Quality Manager (80-100%)

Location: Zurich, Switzerland with occasional travel

In this role as a senior quality professional with experience working in a quality management and assurance role for a medical device company, you will be functioning as an individual contributor and expert resource, that works under limited supervision.

Responsibilities:

Maintenance and continuous improvement of the established Quality Management System at Ava AG. Experience supporting MDSAP and EN ISO 13485 audits required.

Ensure compliance of quality management system with all relevant regulations in the US, Europe, China and other countries

Provide input to the development and update of procedures in light of the revised Medical Device Regulation 2017/745

Support Post Market Surveillance activities; assess potential safety issues, determine whether a potential incident is reportable to competent authorities as per the vigilance system. Ensure compliance with post-market approval requirements.

Be a member of the device development team advising the team on product development, manufacturing changes, technical labeling and ensuring interpretation of the appropriate regulations and technical standards from a quality perspective.

Implementing risk management in accordance with EN ISO 14971 and the internal risk policy.

Review and monitor controlled records supporting the quality management system and advise management/quality of updates to quality management procedures to ensure effective function in line with the Ava's quality objectives;

Assist in corrective action implementation and closure for both projects and quality management system compliance issues;

Communicate Ava's quality system to auditors or customers and promote awareness of applicable regulatory requirements and quality management system requirements throughout the organization;

Conduct of management reviews, internal auditing of established QMS or suppliers as appropriate.

About you:

A bachelor's degree in natural science, engineering, computer science or equivalent from a renowned university

A minimum 5 years of experience in medical device quality assurance.

Sound understanding of quality system requirements – 21CFR 820, EN ISO 13485, Medical Device Single Audit Program.

Experience working as part of a product development team – development and post-production change implementation.

Knowledge of medical software incl. firmware, apps, and cloud-based algorithms are a strong plus

Track record of driving quality assurance and aligning product and organizational environments; previous experience in building up quality management from scratch is a strong plus.

A highly motivated, entrepreneurial and pragmatic personality who enjoys working in a highly dynamic organization with global ambitions

Strong analytical skills to drive complex decisions in an area with a lot of regulatory/quality uncertainties (wearable devices, apps, artificial intelligence, machine learning)

Strong communication skills and the ability to work independently and manage multiple, competing priorities

Motivated to make a real difference in women's health

Fluent in English; additional languages welcome

Motivation to work with advanced IT tools to make processes user-friendly and efficient

EU or Swiss citizen, or valid Swiss work permit

Would you like to contribute to a highly motivated team and benefit from a fast-paced environment at the cutting edge of Artificial Intelligence (AI) for medical devices? If yes, please apply **online** or send your complete application to recruiting@avawomen.com.

We appreciate that you share our excitement for Ava. Please be aware that only complete applications (CV and motivation letter as well as relevant diplomas and work references) can be considered.

Ava – Revolutionizing women's health
Blathnaid Feldman, Director Quality & Regulatory Affairs

Should you not hear back from us within 4 weeks your application has unfortunately not been successful for the respective role.