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 a:

Senior Quality & Regulatory Affairs Specialist (80-100%)

Location: Zurich, Switzerland with occasional travel

Responsibilities:

- Ensure compliance with all relevant regulations in the US, Europe, China and other countries
- Liaise with notified bodies and authorities to support implementation of the global regulatory strategy and expedite regulatory approvals
- Prepare, submit and maintain regulatory dossiers in the US, Europe, China and other countries
- Provide input to the development of technical files and update of procedures in light of the revised Medical Device Regulation 2017/745
- Support Post Market Surveillance activities and ensure compliance with post-market approval requirements
- Advise the device development team as an active member on product development, manufacturing changes, technical labeling and ensuring interpretation of the appropriate regulations
- Implement risk management measures in accordance with EN ISO 14971 and the internal risk policy
- Assess the acceptability of verification and validation documentation for submission
- Review and monitor controlled records supporting Ava's Quality Management System (QMS) and advise management/quality of updates to quality management procedures to ensure effective function in line with Ava's quality objectives
- Assist in corrective action implementation and closure for both projects and QMS compliance issues
- Communicate Ava's QMS to auditors or customers and promote awareness of applicable regulatory requirements and QMS requirements throughout the organization

About you:

- Motivated by our mission to make a real difference in women's health
- Bachelor's degree in natural science, engineering, computer science or equivalent from a renowned university
- A minimum 4 years of experience in medical device quality and/or regulatory affairs
- Track record of driving quality assurance and aligning product and organizational environments Sound understanding of product development incl. clinical trials / Good Clinical Practice (GCP) and how they affect the regulatory approval timeline in different territories
- Strong working knowledge of FDA regulatory pathways (510(k), de novo), CFR 21 Part 820, ISO 13485 and MDR are a must; knowledge of Chinese regulations is a strong plus; any other regulations are a nice to have
- Knowledge of medical software incl. firmware, apps, and cloud-based algorithms are a strong plus
- Highly motivated, entrepreneurial and pragmatic personality who enjoys working in a very dynamic organization with global ambitions
- Strong analytical skills to drive complex regulatory decisions in an area with a lot of regulatory uncertainties (wearable devices, apps, artificial intelligence, machine learning)

- Strong communication skills and the ability to work independently and manage multiple, competing priorities
- Able to work with advanced IT tools to make processes user-friendly and efficient
- Fluent in English; additional languages welcome
- EU or Swiss citizen, or valid Swiss work permit

Would you like to contribute to a highly motivated team, with a lot of space for your own initiatives? 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) 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.