Ava is a digital health company with the aim to revolutionize women's health. The company is headquartered in Zurich, Switzerland with offices in San Francisco and Hong Kong and partner offices in Belgrade and Makati. 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. All delivered in a way that's convenient and non-invasive. Ava is a global, award-winning brand with strong social network communities. Our current key markets include USA, Canada, Germany, Switzerland, Spain, UK, and Hong Kong.

Would you like to join us on our challenging adventure? We are looking for a highly motivated, entrepreneurial and pragmatic personality who enjoys working in a highly dynamic organization with global ambitions. In this key role for our organization, you will take temporarily the lead on all our regulatory affairs to cover for maternity leave starting November 2020.

Senior Regulatory Affairs Manager (60-100%) - Temporary 6 months

Location: Zurich, Switzerland with occasional travel

Responsibilities:

- Ensure compliance of Ava products with all relevant regulations in the US and Europe
- 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 and Europe
- Provide input to the development of technical files and update of procedures in light of the revised Medical Device Regulation 2017/745
- Oversee submission and approval of technical documentation, liaise with notified body concerning review timelines and deficiency responses
- Oversee submission and clearance of US FDA relevant documentation (pre-submissions, 510(k) Traditional, 510(k) Special, Submission Issue Request, Additional Information Requests etc.)
- 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.
- Implementing risk management in accordance with EN ISO 14971 and the internal risk policy
- Assess the acceptability of verification and validation documentation for submission
- 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 throughout the organization

About you:

- Passion for Ava, our community, and our mission to bring women's health to the 21st century
- A bachelor's degree in natural science, engineering, computer science or equivalent from a renowned university
- A minimum 6 years of experience in medical device quality and/or regulatory affairs
- In depth knowledge of FDA regulatory pathways (510(k), de novo), CFR 21 Part 820, ISO 13485 and MDR are a must; any other regulations are a nice to have

- Sound understanding of product development incl. clinical trials / GCP and how they affect the regulatory approval timeline in different territories
- Knowledge of medical software incl. firmware, apps, and cloud-based algorithms are 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 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
- Fluent in English; additional languages welcome
- Motivation to work with advanced IT tools to make processes user-friendly and efficient
- Swiss or EU/EFTA 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 fully documented applications (CV, motivation letter and supporting documents) can be considered.

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

Should you not hear back from us within 3 weeks your application has unfortunately not been successful for the respective role.