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 motivate, 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 the lead on all our regulatory affairs and truly move the needle in this space.

Director Regulatory Affairs

Location: Zurich, Switzerland with occasional travel

Responsibilities:

- Ensure compliance with all relevant regulations in the US, Europe, China and other countries
- Develop and drive global regulatory strategy
- Lead preparation, submission and maintenance of regulatory dossiers in the US, Europe, China and other countries
- Lead regulatory assessment of marketing claims and external communication
- Lead Post Market Surveillance; assess potential safety issues, determine whether a potential incident is reportable to competent authorities as per the vigilance system
- Collaborate closely with key stakeholders incl. internal teams, consultants, and health authorities
- Manage a small, motivated internal team
- Depending on your profile the position may include the responsibility for quality management ("Director Regulatory Affairs and Quality Management")

About you:

- Passion for Ava, our community, and our mission to bring women's health to the 21st century
- Master/PhD in natural science, medicine, engineering, computer science or equivalent from a renowned university
- 8+ years experience in a similar role in the medical device industry
- In-depth knowledge of FDA regulatory pathways (510(k), de novo), CFR 21 Part 820, ISO 13485 and MDR as well as sound understanding of product development incl. clinical trials / GCP and how they affect the regulatory approval timeline in different territories
- Experience with Chinese regulations and medical software incl. firmware, apps, and cloud-based algorithms are a strong plus
- Familiarity with any other regulations, quality management and certification in internal audit are a nice to have
- Excellent communication, people and project management skills to lead the "approval journeys"
- Strong analytical skills to drive complex regulatory decisions in an area with a lot of regulatory uncertainties (wearable devices, apps, artificial intelligence, machine learning)
- Ability to work independently in a fast-paced environment and to manage multiple, competing priorities; comfortable dealing with high pressure at certain time periods
- Fluency in English; German and other European languages are a plus
- 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
Naemi Benz, VP Operations/Maureen Cronin, CMO, VP Research & Development

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