Aspivix is a MedTech start-up with the aim to innovate women's care. The company is headquartered in Renens-Lausanne, Switzerland. Our first device, currently in development, is a new generation of non-invasive surgical instrument for gynecology procedures, designed to reduce pain and eradicate bleeding for women. All that for more than 80 million interventions every year in the world.

Would you like to support us in further developing Aspivix, be among the first employees of a start-up and change women's care for millions of women? If so, join our great team and bring your ideas and your experience to sustainably change the Women's care. For this, we are looking for a:

Regulatory and Quality Affairs (RA/QA) Manager (from 60 to 100%)

Location : Aspivix SA Office, Renens, Switzerland

Responsibilities:

- **Regulatory Affairs:**

- Lead, develop, implement and execute the regulatory compliance and Quality Assurance strategy of the company.
- Lead preparation, submission and maintenance of regulatory dossiers in Europe, US and other countries.
- Communicate with National Competent Authorities and other regulatory bodies.
- Lead regulatory assessment of marketing claims and external communication.
- Lead Post Market Surveillance and Vigilance activities.

- **Quality Affairs:**
  - Management Representative, responsible for implementation, governance, performance reporting and maintenance of the ASPIVIX's quality management system,
  - Ensure compliance to applicable regulatory requirements (e.g. MDR, ISO 13485, US FDA, CFDA).
  - Support R&D with development and maintenance of the technical files according to applicable regulatory requirements (e.g.: Risk Management as per ISO 14971 and Design Controls).
  - Act as the liaison with external parties on matters relating to the quality system that include regulatory/client and third-party audits. Act as Site Management Representative and coordinate all audits, inclusive of schedules, communication, reports and tracking follow-up actions.
  - Develop and maintain the internal audit process as well as suppliers' controls and audits.

About you:

- Master/PhD in science, medicine, engineering or equivalent
- Over 6-year experience in a similar role (Quality Assurance, GMP/GDP and Regulatory Affairs) in the medical device industry.
- In-depth knowledge of FDA regulatory pathways (510(k), de novo), 21 CFR Part 820, ISO 13485, ISO 14971, ISO 14155 and MDR as well as sound understanding of product development incl. clinical trials / GCP and how they affect the regulatory approval timeline in different countries
- Certification as Lead Auditor., to conduct internal and suppliers' audits
- Working knowledge of Process Validation.
- Strong analytical skills to drive complex regulatory decisions.
- Ability to work independently in a fast-paced environment and to manage multiple, competing priorities; comfortable dealing with high pressure at certain time periods in a rapidly changing environment.
- Demonstrate competency in decision-making, flexibility, planning and organizing, self-initiative and interpersonal skills.
- Excellent communication, people and project management skills to lead the approval decisions.
- Fluency in English, additional languages are an advantage.
- Excellent team player in a multicultural environment.
- Willingness to contribute to women's care changes and innovation.

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 jobs@aspivix.com

ASPIVIX – Innovating Women's care

Julien Finci, Chief Technical Officer