Aspivix is a growing MedTech company headquartered in Switzerland. We are innovating and advancing women's health by improving gynecological practice, thus empowering caregivers to deliver a better patient experience. Our first device, currently in development, is a next generation noninvasive device for gynecology, designed to reduce pain and eliminate bleeding for millions of women every year around the world.
Are you ready to join a dynamic environment and an amazing, mission-driven team?

If so, we can't wait for you to join our team and bring your ideas and experience to advance Women's Health.

We are currently looking for a:

Quality Assurance & Regulatory Affairs (RA/QA) Manager - MedTech

Location: Flexible. Aspivix SA Office, Renens (Lausanne Region) and Muttenz (Basel Region), Switzerland

We offer:

- A dynamic working environment as part of a growing start-up in a booming space.

- Working in a MedTech startup which will make a difference in women's health and with a true mission; at ASPIVIX, **we innovate women's care because it is about hefty time for gentler and more modern methods for procedures in gynecology**.
- A possibility to form your own job, build your own team, and to contribute developing products with bigger potential. Your imagination and willingness are the limits.
- Co-operation with a nimble multinational team of brilliant and passionate colleagues.
- A chance to influence from the early beginning the course of a growing company.

About the role:

- **Reporting:**

This position will report directly to the CEO. The RA/QA Manager is part of the Management team.

Medical Specific duties will be determined and coordinated in conjunction with the corporate needs and strategic plans and will be subject to change given ongoing business and clinical research needs.

- **Core Responsibilities:**
  - **Quality Assurance:**
    - 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.

  - **Regulatory Affairs**
    - Develops regulatory strategy for new products (Class I (s)(m)(r) and IIa) and implements plans to obtain FDA clearance/approvals, CE Mark and other foreign regulatory approvals.
    - Manages compliance to all relevant regulations, rules and standards for products and taking part in the conformity assessment procedures with coordination of all concerned departments.
    - Manages conformity assessment process and registration process for products including dossier preparation, submission to Competent Authorities or Notified Body, reviews of application and implementation.
    - Accompanying development projects, issuing development-accompanying and technical documentation for medical devices, revising already existing technical documentations. Maintains regulatory compliance of Technical Files.

- Elaborates and reviews changes to existing Products, SOPs, Test Methods, Process Changes, Design Changes, Labeling/Labels, and Field issues to define the requirements for regulatory submissions and notifications.
- Communication with responsible regulatory authorities (national/international) as well as with notified bodies.
- Lead regulatory assessment of marketing claims and external communication.
- Performs staff training on the topic of regulatory affairs.

- **Leadership Activities**
  - Foster the cooperation between diverse disciplines and functions managing a good balance between discussion, consensus, argumentation and decisiveness.
  - Lead others in the completion of project tasks and sub projects
  - Smooth & facilitate the decision-making process.
  - Create a work environment that supports team effectiveness.
  - Provide feedback to team members.
  - Assist with integration of common tools and techniques.
  - Present to internal and external audiences, including board or investors.

- **Expertise and Problem-Solving Duties:**
  - Identify resource requirements, cost, and time schedules. Develop an implementation plan, conduct risk assessments and develop contingency plans to accommodate unforeseen events.
  - As part of the management team, selects the specific action plans that will best meet the identified business objectives.
  - Be part of the vision and translate vision to project goals, roadmap and plans.
  - Analyze risks, suggest mitigation plans and develop alternatives to solutions.
  - Proactively anticipate and identify risk areas, alert stakeholders appropriately.
  - Able to identify and assess business risks for a given regulatory strategy.

About you:

- **Soft skills:**
  - Is an Excellent team player in a multicultural environment.
  - Shows a “Can-do-attitude” with agility.
  - Has passion for medical device.
  - Self-starter with ability to work independently under pressure and react quickly to changing priorities.
  - Is comfortable with decision process and decision making.
- **Experience & Education:**
  - Master’s degree in life science, engineering or related fields.
  - Five (5) years minimum experience in regulatory affairs in MedTech.
  - Five (3) years minimum experience in regulatory affairs Management in MedTech.
  - Has proven track record in flawless registrations of medical devices in Europe and in the US. Medical device registration in APAC area is a plus
  - Current knowledge of FDA 21 CFR part 820, Medical Device Regulation (MDR 2017 / 745), ISO 13485, ISO 14971, IEC 60601-1, IEC 62366, ISO 11137, ISO 10993

- Strong analytical, planning, and organizational skills
- Strong interpersonal and communications skills (oral & written)
- Experience in Start-up is a strong and determinant plus.
- Fluency in English. German or French is a plus.

Should you want to contribute to a highly motivated and passionate team, with a lot of space for your own initiatives, send your complete application to jobs@aspivix.com

ASPIVIX – Innovating Women's care

Mathieu Horras, CEO

ASPIVIX is an equal opportunity employer committed to diversity. Each recruitment decision we make for people we hire is based solely on the candidates' knowledge, experience and skills.