ASPIVIX
INNOVATING WOMEN'S CARE


Aspivix is a growing MedTech aiming at innovating and advancing women's care to enable an improved gynecological practice, empowering caregivers to deliver better patients' experience. The company is headquartered in the Lausanne region, Switzerland. Our first device, currently in development, is a new generation of non-invasive instrument for gynecological procedures, designed to reduce pain and eliminate bleeding for millions of women every year in the world.

Are you ready to join a dynamic environment and an amazing team driven by the passion to improve Women's care for millions of women?

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

We are currently looking for a:

# Regulatory Affairs Manager - MedTech

Location: Aspivix SA Office, Renens (Lausanne Region), Switzerland

**We offer:**

- A dynamic working environment as part of a start-up.
- 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 we believe that women deserve gentler and more modern methods for procedures in gynecology**.
- A possibility to form your own job 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.

This role is a position creation. The Regulatory Affairs Manager, after joining the company, will work in close collaboration with the QM Manager of the company.

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.

- **Responsibilities:**
  - **Core Responsibilities**
    - 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 62364
  - 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.