ASPIVIX
INNOVATING WOMEN'S CARE

Aspivix is well-funded and growing MedTech that is innovating women's care to enable an improved gynecological practice for caregivers and a better experience for patients. The company is headquartered in the Lausanne region, Switzerland. Our first device, currently in development, is a new generation of non-invasive surgical instrument for gynecological 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 be part of a small but amazing team to improve Women's care for millions of women ? If so we are waiting for you, join our team and bring your ideas and experience to sustainably advance the Women's care.

We are currently looking for a:

Sr. R&D Project Manager Medical Device

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

We offer:

- A challenging and 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 is the limit.
- A possibility to participate to the development and the launch of a medical device from idea to production.

- Co-operation and exchange of ideas within a small but multinational and interdisciplinary team of brilliant and passionate colleagues.
- A chance to influence from the early beginning the course of growing company.

About the role:

- **Responsibilities:**
  - **Core Responsibilities**
    - Lead projects from concept to commercialization, leading a cross-functional team to execute projects with sound problem-solving methodology; track project and program status and results; remove and elevate project barriers for the team.
    - This position will require creation of detailed project plans, resource and budget management, schedule management, and project documentation including Design History Files & phase gate reviews in accordance with internal Design Control requirements.

  - **Leadership Activities**
    - Foster the cooperation between diverse disciplines and functions managing a gool balance between discussion, consensus, argumentation and decisivness.
    - 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. Provides feedback to team members.
    - Assist with integration of common tools and techniques.
    - Prepare and present reports and other presentations to internal and external audiences, including senior management, 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. Assist management in selecting the specific action plans that will best meet the identified business objectives.
    - Be part of the vision and translate vision to project goals to project roadmap & plans.
    - Analyze risks and suggest mitigation plans. Develop alternatives to business problems.
    - Proactively anticipate and identify risk areas and alert stakeholders appropriately.

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
  - Is comfortable with decision process and decision making.

- **Experience & Formation:**
  - Master/PhD in science, engineering (Mechanic, Biomedical or related fields) or equivalent. PMP Certification or equivalent is a plus.
  - Minimum 5 years of R&D Project Management in medical industry, experienced with:
    - Design Controls for Medical Devices Class I & II.
    - ISO 13485 compliant Quality System.
    - 21 CFR Part 820, Quality System Regulation.
    - Human Factor Engineering IEC 62366.
    - Risk management ISO 14971.
    - Notify Body, CB Report, UL & CE Marking, 510(k) submission.
    - Electrical Safety 60601 is a plus.
    - CAPA & prodcution processes NCR, SCAR, IQ/OQ/PQ.
  - Experience in Start-up is a strong and determinant plus
  - Experienced in leading cross-functional teams (Clinical, Regulatory, Operations, R&D, etc.) to successfully achieve goals.
  - Fluency in English. German / 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, apply online or send your complete application to jobs@aspivix.com

ASPIVIX – Innovating Women's care

Mathieu Horras, CEO & Julien Finci, CTO