



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? For this development project we are looking for a:

Mechanical Industrialization Engineer

Location: Aspivix SA Office, Renens, Switzerland

Responsibilities:

- Actively contribute for the mechanical design and design changes
- Lead the industrialization phase for a MedTech Class Is device until product launch in collaboration with the Chief Technical Officer
- Drive activities requiring mechanical changes to sustain the product after launch



- Take major decisions for the mechanical development of the next generation of instrument and contribute to the ASPIVIX's roadmap
- Translate business and user requirements into technical solutions, review and actively contribute to system requirements and identify non-functional requirements early in the development process
- Develop and update technical documentation from User requirement to verification and validation
- Document detailed designs in compliance with ASPIVIX's QMS and regulatory requirements (MDR, ISO 13485, V-model, US FDA, C-FDA) and be responsible for technical risk management
- As well as development and maintenance of the technical files according to SOPs and international standard ISO/FDA (DHF-DMR-DHR)
- Manage external suppliers (CMO, Regulatory...)
- Launch and lead new R&D project(s) with academic institutions (EPF/ETH, HES/FH, ECAL...)
- Actively support the development team with regulatory, quality, technical engineers, external suppliers and manufacturing
- Identify intellectual Property (IP) opportunities and strengthen company IP

About you:

- Bachelor/Master in Mechanical engineering HES/FH / EPF/ETH or equivalent qualification
- +3-year working experience as a professional developer in medical devices industry
- Fluency in English, additional languages are an advantage. Excellent written communication skills in English for technical documentation
- Excellent knowledge of CAD Design and tools such as e.g. CATIA, Solidworks, Solidedge, ProEngineer or equivalent
- Excellent understanding and solid experience of plastic injection molding and in molds manufacturing
- Excellent understanding of plastic manufacturing and assembly methods
- Experience with rapid prototyping technologies and limitations
- Industrialization know-how, verification, validation and qualification
- Experience in polymers choices and characterizations
- Solid experience in simulation e.g. Comsol/Ansys (geometry, stress, temperature, flow etc.) and Mathcad, Matlab or other
- Experience in Product Risk management and Usability engineering, D-FMEA, P-FMEA
- Broad technical knowledge and willingness to learn new things
- Excellent written and verbal communication skills with the ability to adjust to the audience
- Willingness to work flexibly, in an interdisciplinary environment
- Strong analytical skills and process-oriented work style with a structured, independent approach to work and focus on getting things done
- 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