aspivix
Medical Solutions for Women's Health

Join the Adventure to Advance Women's Healthcare!

Position: Quality Assurance Specialist (Junior) - MedTech

Aspivix is a mission-driven, women's healthcare company based in Lausanne, Switzerland dedicated to bringing modern medical devices to gynecology. Aspivix is global, fast-paced and run by an accomplished team who are passionate about making a dent in gynecology.

About the role…

The position of **Quality Assurance Specialist (Junior)** will report directly to the Regulatory Affairs and Quality Assurance manager.

- **Support activities to ensure compliance to applicable quality requirements regulated by ISO 13485 and US FDA 21CFR820:**
  - QMS documents update,
  - Non-Conformities,
  - CAPAs, analysis, implementation, reporting,
  - Post Market Surveillance, collecting data from the market, managing FSN/FSCA and creating trend reporting (statistical analysis and reports),
  - Complaint collection, registration, management,
  - Audits (schedules, communication, reports and tracking follow-up actions).
  - Keep the team updated and trained on the existing QMS and any update.

- **Support quality engineering activities:**
  - Identify and update of Standards and guidance applicable to the projects,
  - Review of relevant design control documentation (user requirement specifications, design input requirements, design output, design verification and validation, risk management and usability documents, etc.),
  - Manage changes to SOPs, Templates, Test Methods, Process Changes, Design Changes, Labeling/Labels, and Field issues.

- **Leadership Activities**
  - Foster cooperation between diverse disciplines and functions managing a good balance between argumentation, consensus, and decisiveness.
  - Facilitate the decision-making process.
  - Create a work environment that supports team effectiveness.

About you…

You are definitely a match if you have…

- **Soft skills:**

- Quality oriented.
- Curious to learn and grow.
- Shows a "Can-do-attitude" with agility.
- Excellent team player in a multicultural environment.
- Has passion for the medical device world.
- 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.
  - Minimum 2-year experience in Quality Management System for MedTech.
  - Knowledge of FDA 21CFR820 and 510k filing, Medical Device Regulation 2017/745(MDR), and ISO 13485. A certified training on ISO13485 is a plus.
  - Experience with NB interactions is a plus.
  - Knowledge of ISO 14971, IEC 60601-1, IEC 62366-1, ISO 11137, ISO 10993, IEC 62304 is a plus.
  - Strong analytical, planning, and organizational skills
  - Strong interpersonal and communications skills (oral & written)
  - Experience in Start-up is a plus.
  - Fluency in English. German and/or French is a plus.

About the offer…

- Opportunity to get exposure and first hands-on experience in some of the most audited topics of a medical device quality management system according to ISO 13485; US FDA 21CFR820; Regulation (EU) 2017/745 (EU MDR). You will contribute to managing and improving the QMS by getting in touch with all the team's subject matter experts. It is the opportunity to first look into the Regulatory Affairs topics and Risk Management under ISO14971.
- Flat hierarchy, short decision-making processes, interdisciplinary collaboration.
- Versatility to contribute and develop your skills in an agile company.
- A possibility to make meaningful impact for women's health and contribute to developing products with bigger potential. Your imagination and willingness are the limits.

Location…

Flexible. Aspivix SA Office, Renens (Lausanne Region) and Muttenz (Basel Region), Switzerland. Possibility to work remotely part of the weekly working time.

If this sounds like you then what are you waiting for!

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

Mauro Rinaldi
RA/QA Manager

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