Puzzle Medical
Devices

JD–040

MONTREAL, Design Quality Engineer, full-time, in-person

Puzzle Medical is developing a percutaneous heart pump for patients with advanced heart failure. The device's modular design allows for safe percutaneous implantation to support both renal and cardiac function through 4mm-pumps anchored in parallel in the descending aorta, allowing stability for patient mobility, mechanical hemodynamic support, helping patients with increased accessibility, improved quality of life, and reduced hospitalizations. To date, Puzzle Medical has successfully: completed a Seed financing round (2022); completed a Series A financing round (2023); completed its 4 patients first-in-human study with all patients experiencing improvements in cardiac and kidney function (2022); received U.S. Food and Drug Administration (FDA) Breakthrough Device Designation (2021).

SUMMARY

As a Design Quality Engineer, you will play a critical role in ensuring that our devices meet the highest standards of quality and safety from the initial design phase through to production. Your expertise will be vital in developing and implementing quality plans, conducting risk assessments, and ensuring compliance with regulatory requirements. This position offers an exciting opportunity to contribute to the advancement of life-saving technology and make a tangible impact on patient care.

RESPONSIBILITIES

- **Quality Planning and Control:**
  - Develop and implement quality plans, standards, and procedures for new product designs.
  - Collaborate with design and development teams to ensure that quality is built into the product from the beginning.
- **Risk Management:**
  - Conduct risk assessments and failure mode and effects analysis (FMEA) to identify potential design issues.
  - Develop mitigation strategies to address identified risks.
- **Verification and Validation:**
  - Plan and execute design verification and validation activities, including testing and inspection of prototypes.
  - Ensure that the product meets all specifications and regulatory requirements.
- **Documentation and Compliance:**
  - Maintain detailed records of design reviews, test results, and quality control activities.
  - Ensure compliance with industry standards and regulatory requirements (e.g., ISO, FDA).
- **Continuous Improvement:**
  - Analyze quality data and feedback to identify areas for improvement in the design process.
  - Implement changes to improve product quality and reduce defects.
- **Problem Solving and Root Cause Analysis:**
  - Investigate design-related quality issues and conduct root cause analysis.
  - Develop and implement corrective and preventive actions.
- **Cross-Functional Collaboration:**
  - Collaborate with other departments, such as manufacturing, procurement, and regulatory affairs, to ensure a holistic approach to quality.
- **Training and Support:**
  - Provide training and support to design and development teams on quality-related topics.
  - Promote a culture of quality within the organization.

QUALIFICATIONS

- Strong knowledge of design control processes, risk management, and regulatory standards
- Bachelor's degree in Engineering, Quality Assurance, or a related field (Master's degree preferred).
- Minimum of 3 years of experience in design quality engineering, preferably in medical devices.
- Expérience dans un environnement certifié dans une entreprise conforme à un standard de qualité (ISO 9001, ISO 13485 ou ISO 17025)
- Experience with quality management systems and documentation practices.
- Excellent problem-solving skills and attention to detail.
- Strong communication and interpersonal skills, with the ability to collaborate effectively across teams.