MONTREAL, DIRECTOR OF QUALITY AND REGULATORY AFFAIRS

INDUSTRY

Medical Devices

EMPLOYMENT TYPE

Full-time

Puzzle Medical is a Canadian company specializing in the development of a minimally invasive long-term hemodynamic transcatheter pump. Puzzle Medical enables mechanical hemodynamic support to be more efficacious, safer, and more economical, resulting in increased accessibility, improved patient quality of life and reduction of the global economic burden related to the disease.

Founded in 2018, Puzzle Medical has successfully completed in vivo preclinical trials and raised funding from Canada, United States and Europe.

Our mission is to increase global health by delivering safer treatment alternatives through breakthrough technologies.

SUMMARY

To manage quality/regulatory affairs activities of a medical device class III, and implement a complete Quality Management System (QMS) to support the development and commercialization of ModulHeart in compliance with applicable regulations in the United States, Canada and Europe. Understand the requirements for the development, verification and validation of the device.

RESPONSIBILITIES

- Establish and revise QMS SOP's and Quality Manual within the company.
- Supervise and coordinate all QMS activities with internal and external stakeholders.
- Provide training to new and existing employees on QMS and regulations.
- Ensure oversight of the Design History File (DHF) and Device Master Record (DMR).
- Plan, organize and execute quality management reviews.
- Write regulatory submissions for FDA/Health Canada/EU.
- Maintain an understanding of regulatory compliance requirements and changes as mandated by the countries we will commercialize in.

EDUCATION AND WORK EXPERIENCE

- Bachelor's degree or Master's degree (preferred)
- Excellent understanding of medical device regulatory requirements (FDA/ISO/Health Canada/EU)
- Lean Six Sigma experience is a plus
- Experience and knowledge of Good Manufacturing Practices
- Proven experience writing SOP's
- Bonus: Regulatory affairs certification, ISO13485 auditor training

INDUSTRY EXPERIENCE

- 5-10 years of experience in Quality Management focused on Medical Devices and Regulatory affairs with FDA/Health Canada/EU.

COMPETENCIES

- Ability to understand the technical aspects of the company's medical device.
- Ability to manage a project dealing with several subjects at the same time.

- Effective planning and organizational skills.
- Structured, rigorous.
- Problem solving skills.
- Proven record of successful completion of tasks with minimal supervision.
- Superior interpersonal, communication and leadership skills.

WANT TO JOIN US ? CONTACT US !

Send your CV at careers@puzzlemed.com and we'll reach out shortly !