TRANSFORMING WOMEN'S HEALTH WITH LIFE-CHANGING, PERSONALISED, MEDTECH HORMONE-FREE SOLUTIONS FOR INTIMATE HEALTH

The women's health market is large & underserved a market ripe for disruption. AVeta Medical's vision is to help women manage & embrace the body's hormonal shifts shamelessly. AVeta Medical's CEO & Founder completed the BioInnovate Ireland & Fellowship in 2017 & has since developed patent-protected technologies that solve one of the most significant unmet needs in the women's health space. She has established a leadership team with direct experience in launching new products in women's health & a Clinical Advisory board of Key Opinion Leaders in women's health. Our long-term mission is to establish a global women's health platform with personalised solutions at every stage in a woman's life.

AVeta Medical is based in Galway, Ireland, a vibrant medtech innovation hub. It is a spinout of NUI Galway, developing a device targeting the 39m women who suffer from vaginal atrophy, a global market of c€2.5B. We have already completed proof of concept preclinical work in rodent & ovine models & in 2021 AVeta Medical was awarded the EIC accelerator grant of €2.5M which will fund our first clinical evidence study this year in advance of our first funding round. We are aiming to launch our first product into the US market in 2024 & the European market in 2025.

WE ARE NOW RECRUITING A DIRECTOR OF QUALITY ASSURANCE &REGULATORY AFFAIRS (QARA)

Are you an experienced Manager/Director of QARA seeking a new challenge?

As a key early employee in a valuable leadership position, you will be joining a senior leadership group steering the company's growth, value & culture. The Director of Quality Assurance & Regulatory Affairs will own & shape the Regulatory & Quality System functions at AVeta Medical. The appointee will be the main point of contact for regulatory authorities & notified bodies for the market introduction in 2024 of a Class II medical device, alongside a future pipeline of high-impact, patient-focused woman health products.

This is a full time, permanent role based in Galway, Ireland with a hybrid work-from-home opportunity & flexible working hours. Limited travel will be required depending on the project phase. The Director of QARA will report directly to the CEO. A highly competitive remuneration package is available commensurate with experience & incorporating share options to enable the successful candidate to share in the company's overall value as we grow.

DUTIES & RESPONSIBILITIES

- Responsible for the development, implementation & maintenance of AVeta Medical's Quality Management System (QMS) to ISO 13485 for its medical devices & oversee employees & contractors/partners in using the QMS.
- Develop regulatory approval strategies for a Class II medical device in the US, Europe and ROW to ensure rapid translation of benchtop R&D to clinical implementation. Have hands-on ownership of regulatory submissions for clearance/approval.
- Set up & implement the day-to-day activities within the business' Quality Management System.
- Ensure Quality System processes are lean, compliant, user-friendly & are well understood throughout the organisation.
- Enhance a compliance culture throughout the organisation. Carry out training & communication activities with employees and stakeholders on current & new regulatory requirements to ensure adequate understanding of Quality Systems, Regulatory requirements & product compliance.
- Lead the team in identifying key regulatory & quality risks, identifying mitigation strategies, & reporting on these regularly to the wider team. Develop a risk register for internal risk management & for submission to regulatory authorities.
- Draft & lead ethics & regulatory approval documents for clinical studies.
- Negotiate with regulatory authorities throughout the product lifecycle.
- Provide input into overall company strategy as a member of the senior leadership team.
- Manage external and internal audits.

EXPERIENCE REQUIREMENTS –The Ideal Candidate Must have:

- Expert knowledge of ISO 13485, ISO 60601, ISO 14971, FDA Quality System Regulation, FDA 510k and De Novo Pathways, and EU MDR.
- Direct experience in leading the regulatory submission of medical device projects through FDA 510k clearance or De Novo approval. You have personally prepared and submitted materials to the FDA for clearance/approval of a medical device.
- Direct experience in interfacing with clinical teams in the regulatory approval of clinical studies. You have personally prepared and submitted materials for regulatory authority approval of in-human clinical studies of a medical device.
- Direct experience of implementing a Quality Management System within a medical device development environment.
- Demonstrated people management skills, preferably within a Medtech environment. You are able to show examples of interfacing with R&D, Operations and Clinical teams to ensure regulatory and quality requirements are met.

ATTRIBUTES

- A proactive team player with exceptional leadership qualities with a strong ability to plan & prioritise multiple deadline-based projects in a hands-on manner.
- Excellent analytical abilities coupled with outstanding written, verbal communication & collaboration skills.
- Good at determining the processes necessary to get things done; can simplify complex processes.
- Critical attributes include creativity, initiative, a hands-on approach & multitasking.
- Willing to adopt, engage with &shape company culture in a positive manner.

Our Values are important and we want to hear from people who share them:

- **Patient First:** A commitment to the delivery of safe and effective solutions that significantly improve quality of life. A genuine passion to improve women's lives.
- **High-Quality Customer Delivery:** To deliver a high-quality sustainable product and service at a reasonable price.
- **Purposeful Innovation:** To use scientific research to understand unmet clinical needs and develop scientific solutions.
- **Employee Enrichment:** To provide a respectful, inclusive and entrepreneurial environment where employees can thrive with calculated bias for action & where all the employees are valued, supported, & encouraged. A collaborative teamwork environment where learning is constant & performance is rewarded.

At AVeta Medical, we value what makes you unique. Be part of an innovative woman's health start-up that thinks differently to solve problems and deliver meaningful innovations. We are an equal opportunities employer and respect the importance of bringing different skill sets and perspective together to generate the best solutions.

What's next:

- **Send your CV and the reasons why you're a great fit for this job to paula.newell@nuigalway.ie**