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

The women's health market is large and underserved, a market ripe for disruption. AVeta Medical's vision is to help women manage and embrace the body's hormonal shifts shamelessly. AVeta Medical's CEO and Founder completed the BioInnovate Ireland Fellowship in 2017 and 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 and 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 and ovine models and 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 2025 and the European market in 2026.

WE ARE NOW RECRUITING FOR A SENIOR RESEARCH & DEVELOPMENT ENGINEER

The Senior R&D Engineer will help shape the product development cycle of the proprietary AVeta device for the treatment of vaginal atrophy for postmenopausal women and Breast Cancer Survivors. As a Senior R&D Engineer you will be a key member of the engineering team working within a multidisciplinary framework. This role offers applicants the chance to work with a focused team in a fast-paced environment to deliver exciting and meaningful medical devices that matters most to women.

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

DUTIES & RESPONSIBILITIES

- Lead and be an integral part of the team tasked with the development process from concept generation through design freeze, design verification/validation to commercialization.
- Assist in the development of intellectual property generated by development activities.
- Ensure the application of new and existing technologies to provide the optimum design for efficacy and manufacture.
- Execute structured problem-solving methodologies.
- Participate in clinical trials with physicians to provide clinically relevant feedback on product designs.
- Provide technical feedback during frequent technical contact with customers to optimize product design.
- Execution and maintenance of product design files and other relevant documentation to comply with ISO 13485 and 21 CFR 820 quality standards.
- Compile technical project plans to develop devices in accordance with planned activities, budget, and timelines.
- Execute technology transfer to the manufacturing, interfacing effectively with manufacturing subcontractors and other suppliers to deliver on agreed product specifications.
- Manage any external contractors to deliver on time, cost and performance targets.
- Travel required to meet with KOL's and CRO for clinical trial activity.
- Work with the leadership management team to develop further grant applications for product development opportunities.

KEY REQUIREMENTS

- Level 8 engineering, science, or equivalent degree.
- 7 to 10 year's industry experience in a medical product development environment with a proven track record of leading teams in novel and innovative device development.
- Experience of coordinating and leading Design Reviews and the compilation of associated documentation.
- Demonstrate a thorough knowledge and understanding of ISO 13485 & FDA 21 CFR Part 820 Design Control requirements.
- Proven experience in performing Hazards Analysis, AFMEA and D/PFMEA's, verifications and validations for medical devices products and processes.
- Knowledge and experience with Medical Device design including packaging and validation.
- Proven experience of work with IEC 60601 standards.
- Experience with engineering tools for systematic problem solving such as DMAIC, DOE, and using Minitab and Minitab workspace.
- 3D modelling with surfacing experience.
- Working knowledge of biocompatible polymer materials.
- Apply an understanding of anatomy and physiology with engineering knowledge in materials and processes to come up with working designs.
- Demonstrate a working knowledge of the required activities and deliverables from each of the development phases.
- Prior experience of bringing a medical device through the full development cycle including clinical studies/regulatory approval.
- Experience in working with KOLs to identify unmet therapy needs.

ATTRIBUTES

- Effective planning mentality and results focus. Objectively prioritizes product development opportunities. Excellent attention to detail and bias towards action.
- Ability to thrive in a start-up environment and willingness to adapt to a small company environment.
- Outstanding written and verbal communication both internally and externally. Communicates complex technical challenges appropriately and effectively.
- Effective at building strong cross-functional relationships with the key stakeholders.

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, personalised solutions that matter most to our end users.
- Employee Enrichment: To provide a respectful, inclusive, and entrepreneurial environment where employees can thrive with calculated bias for action.

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@avetamedical.com