Join Viecura: Regulatory Affairs Specialist

About Us: Viecura Group is a vibrant and expanding Class 1 Medical Device manufacturer. As a core strategic manufacturing partner to some of the world's largest healthcare companies, Viecura is at the forefront of innovation within our core Class 1 medical device product areas. At Viecura, we value what makes you unique. Be part of a company that thinks differently, with a clear focus on innovation to deliver genuine patient centric product solutions

Join Viecura Group and be part of a dedicated team that provides patient focussed healthcare solutions, values diversity, inclusion, and personal ambition, and is reshaping the future of healthcare, one innovative product at a time.

Position Summary: Viecura is expanding our team in Ireland and we are seeking a talented individual to join us as Regulatory Affairs Specialist.
This role will be based in Dungarvan, County Waterford, and you will play a pivotal role in ensuring implementation, maintenance, and compliance to regulatory standards. We are open to applications from both experienced applicants and to recent graduates with the relevant professional qualifications.

Your Role: As a Regulatory Affairs Specialist, you will have a multifaceted role with a range of direct responsibilities:

Regulatory Affairs Function:

- Develop strategic regulatory plans for project teams, ensuring approvals in EU.
- Support your colleagues in both the commercial and product development functions.
- Coordinate submissions of product registration documents and interact with regulatory agencies and maintain compliance with MDR and FDA requirements.
- Develop and direct site quality systems and procedures.
- Monitor implementation of the quality management system in the EU region.
- Train and support colleagues on quality management system procedures.
- Scale up quality compliance operations to support EU growth.
- Provide strategies to address compliance gaps and enhance quality systems.

Key Skills & Experience:

- Bachelor's degree in chemistry or related life science field.
- Knowledge of regulatory compliance, MDR and FDA.

- Understanding of QMS, including ISO 13485 and ISO 14001.
- Self-motivated, team-oriented, and flexible.
- Effective interpersonal, verbal, and written communication skills.
- Strong problem-solving, analytical, and project planning skills.

Why Join Us: At Viecura, you will be a valued team member with an ambitious company that values innovation, collaboration, and personal growth. We provide opportunities for professional development, a positive and supportive working team environment, and the chance to make a meaningful impact in healthcare.

Viecura Offers:

Job Type: Full-time, Permanent, Dungarvan on site.

- A Competitive Salary
- 25 days Holidays
- An opportunity for career development in a fast-growing company.
- Opportunities for professional and personal development.
- Travel to Viecura facilities and healthcare industry partners in China, USA, and EU.
- Year End Bonus
- Additional leave
- Bike to work scheme
- Company events
- On-site parking

How to Apply: If you are ready to join Viecura in shaping the future of patient centred healthcare products, please contact us.

Candidate applications : info@viecuragroup.com include your CV and cover letter

Viecura is an Equal Opportunity Employer.