SENIOR REGULATORY AFFAIRS SPECIALIST

Cork, Ireland

The Company

This company has been voted over and over again to be one of the best employers in Medtech!
This company offers security, stability and long term career opportunities.
The diverse team is very collaborative and you can expect to participate in team building activities such as; cooking classes, boat cruises and even escape rooms!
This position is all about supporting product development projects to deliver regulatory strategy across Europe, the US and internationally.
The products are implants, class III, and even some combination products!

The Role

Owing to a recent acquisition and big pipeline of product development, a new role has been created. This is a great chance to be part of something that you can shape yourself, not having to fit into someone else's shoes! You will have a unique exposure to the US and build a great portfolio of experience that will really give you some great long term career options.
With 60% of your time focussing on new product development projects, you will be at the centre of innovation.

As Senior Regulatory Specialist

- Be responsible for ensuring compliance to EU, US and international regulations, for your portfolio of medical devices.
- Work together with the FDA, Notified bodies and other regulators to ensure regulatory approval
- Author 510(k) submissions for regulatory approval in the US markets
- Follow the development of high risk medical devices, from concept to market approval, i.e cradle to grave.
- Support other partners from the company as the subject matter expert for your own portfolio of medical devices
- Work on cross functional teams; R&D, marketing and manufacturing to advise the regulatory impact of proposed product changes and transfers

Do you have

- 2 - 6 years experience in Regulatory affairs with medical devices?
- Experience with class III device? Or class IIb implantable products?
- Experience successfully obtaining, CE mark?
- An interest to work with the US FDA?

If you want to join a multicultural regulatory team of international experts, benefit from excellent training, and work with state of the art medical devices, get in touch!

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