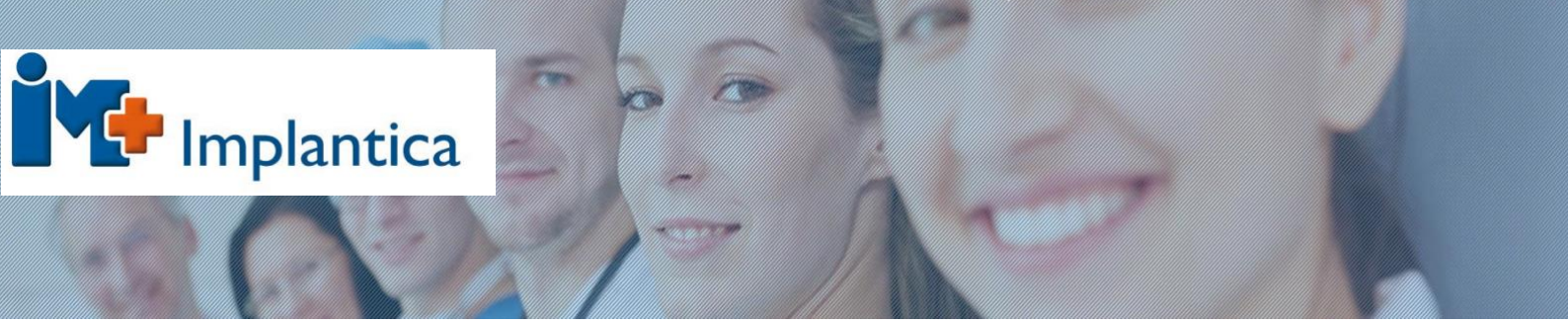


About Implantica Group

With over 10 years of extensive research and development work, with operations in the heart of Switzerland along with subsidiaries in the US and other countries, Implantica has been at the forefront of disrupting the field of smart medical implants and eHealth technologies.

Our ambition to make a noticeable contribution to mankind is already one step closer to becoming a reality with the introduction of our first breakthrough technology, RefluxStop™, a paradigm shift in the treatment of GERD (Gastroesophageal reflux disease) that affects more than 400 million people worldwide.

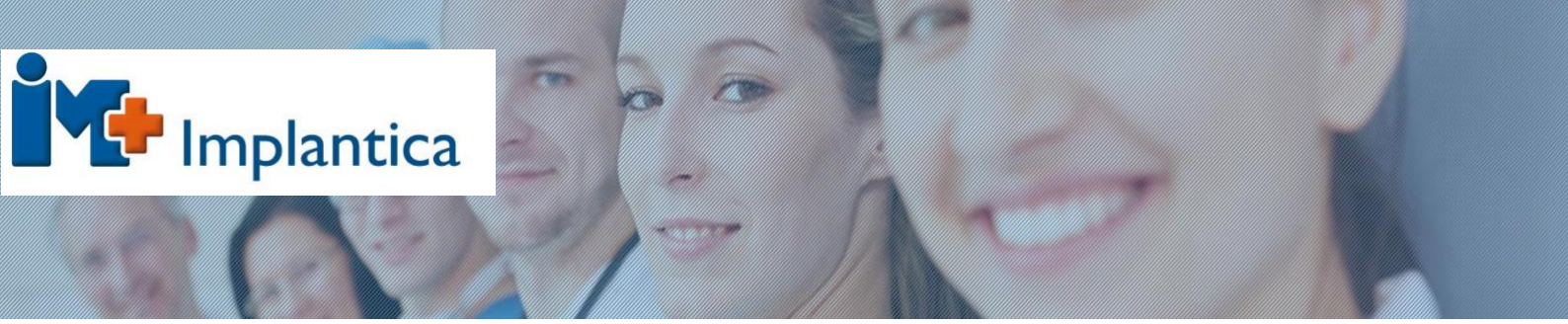
RefluxStop has received CE mark and is now commercially available in key European countries and receiving encouraging feedback from regulatory bodies in other key regions where we are seeking market approval. As our company is continuously growing, we are seeking immediately or by agreement for a

Senior Manager Regulatory Affairs (m/f), 100%

(Remotely based)

Key Responsibilities:

- Prepare documentation and lead medical device regulatory submissions in accordance with FDA requirements (e.g.: pre-submissions, original PMAs, PMA supplements, PMA Annual Progress Reports, 510(k)s, facility registration, listing)
- Create and maintain technical files and regulatory dossiers for CE marking and to achieve international regulatory approvals and registrations
- Act as an active regulatory representative on project teams and provide regulatory expertise to support the company's new product innovation portfolio
- Determine regulatory strategies for accessing new markets, launching new products and maintain licences, registrations and regulatory compliance through to the end of the product life cycle
- Review and analyse technical protocols, data and reports generated by research and development, operations, clinical, quality and other departments.
- Review and approve proposed labelling, packaging, advertising and promotional materials after evaluating conformance to regulations.



Your Profile:

- University degree or equivalent in an engineering, life sciences, or another relevant scientific discipline
- At least 5-7 years practical (hands-on) experience in a medical device regulatory environment, preparing submissions (PMAs/PMA Supplements, 510(k)s and Design Dossiers/Technical files) for Class II and III medical devices and a successful track record is required
- Experience interacting with USA FDA and European Notified Bodies is required
- Comprehensive Knowledge of Design Control processes, Quality and Regulatory Standards needed in the medical device environment
- Ability to effectively work with employees in different locations, internal and external stakeholders, and manage consultants and local country representatives
- Fluent verbal and written English

We offer you:

- A challenging and exciting position in an open and dynamic company
- A motivated, dedicated and international team
- A long-term commitment
- Modern working conditions and competitive remuneration

Interested?
Then send your complete application documents by mail to careers@implantica.com or via LinkedIn Easy Apply. For more information visit www.implantica.com.

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