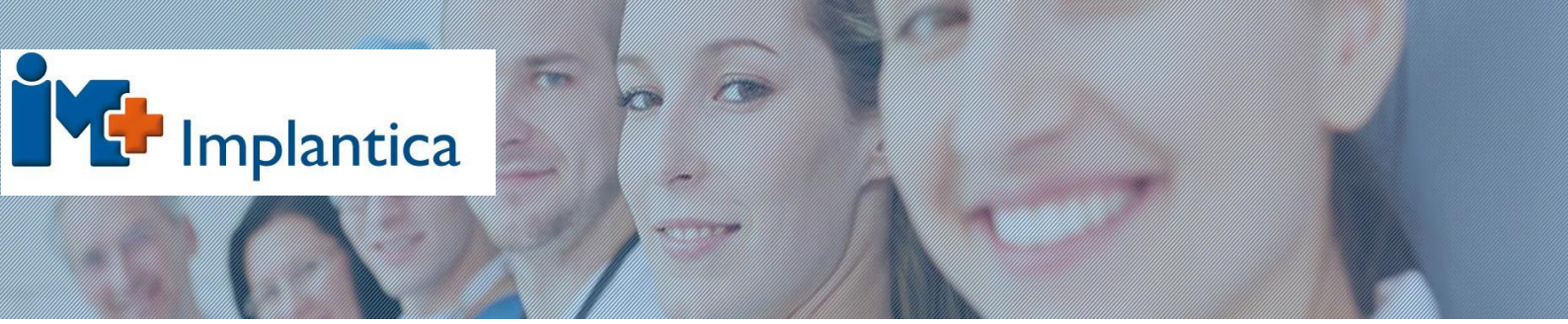


About Implantica Group

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.

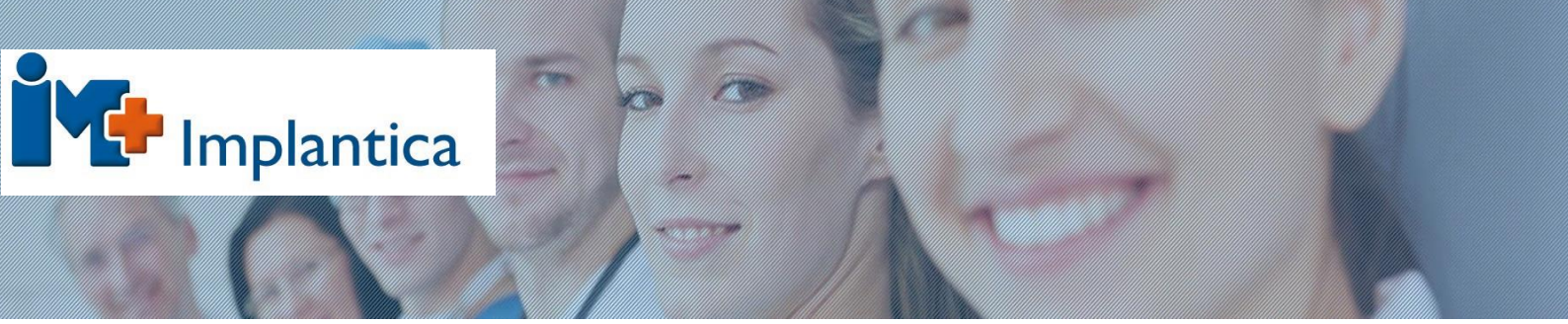
RefluxStop has received CE mark and is now commercially available in key European countries and receiving encouraging feedback from regulatory bodies in other key regions where we are seeking market approval. As our company is continuously growing, we are seeking immediately or by agreement for a Verification and Validation Engineer, 100% (m/f).

Verification and Validation Engineer, 100% (m/f).

This position would be based in Zug, Switzerland, however remote work from another EU/ UK country can be considered for an ideal candidate.

Key Responsibilities:

- Support to FDA PMA submission review and responses
- Support in preparation of pre-clinical internal testing and testing by external laboratories
- Provide focused, technical, hands-on engineering assistance regarding V&V requirements of medical device processes, materials, equipment and methods including project management, process design, document generation (IQ, OQ, PQ, SOPs, WIs and ETSs), critical process parameter development, protocol execution and summary reports
- Responsible for managing the packaging, transportation and shelf-life testing by external service providers
- Preparation of documentation and use of statistical techniques, as necessary, to properly design and execute V&V activities, with focus on the US Code of Federal Regulations (CFR) and guidelines, such as 21 CFR 820.75
- Prepare documentation and execute V&V activities utilizing a risk-based approach ensuring compliance to medical device industry regulations
- Participate in the review and qualification of external supply chain V&V activities



Qualifications:

- University degree or equivalent in an engineering, life sciences, quality or another relevant scientific discipline
- In-depth knowledge of the following: 21 CFR 820 and FDA Device Approvals and Clearances preferably PMAs, ISO13485, ISO 14971, IEC 62366, FDA Guidelines on general principles of process validation, 1987, STAT-09 Statistical procedures, etc.
- Experience in medical device manufacturing and medical standards is highly desirable.
- Excellent command of English both verbal and written
- Ability to effectively prioritize and execute tasks in a high-pressure environment

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.

Implantica Management AG
Industriestrasse 24, CH-6300 Zug, Switzerland
T: +41 41 539 19 00/ www.implantica.com