WYSS CENTER

Job Description

Job title: Regulatory & Clinical Affairs Engineer
Position: Permanent (100%)
Posted on: 15th October 2020
Job location: Wyss Center for Bio and Neuroengineering in Geneva, Switzerland

About the Wyss Center for Bio and Neuroengineering, Geneva, Switzerland
The Wyss Center is an independent, non-profit research and development organization that advances our understanding of the brain to realize therapies and improve lives.
The Wyss Center staff, together with the Center's academic, clinical and industrial collaborators, pursue innovations and new approaches in neurobiology, neuroimaging and neurotechnology.
Wyss Center advances reveal unique insights into the mechanisms underlying the dynamics of the brain and the treatment of disease to accelerate the development of devices and therapies for unmet medical needs.
The Wyss Center was established by a generous donation from the Swiss entrepreneur and philanthropist Hansjörg Wyss in 2014. Additional resources from funding agencies and other sources help the Wyss Center accelerate its mission.

About the Position
The **Regulatory Affairs & Clinical Affairs (RA&CA) Engineer** will work both independently and collaboratively at the Wyss Center to facilitate the development of advanced implantable neurosensing and neuromodulation devices that are designed to collect real-time neural signals, to transmit multichannel recordings and to provide closed loop control signals for a range of applications.

More specifically, the individual will contribute to the regulatory activities of the Wyss Center, such as preparation of technical documentation for study submission to regulatory authorities for clinical studies and/or CE marking, as part of the Wyss Center's mission to develop and translate to the market innovative medical devices and therapies. The RA&CA Engineer will work with the Clinical Affairs Specialist to review and provide inputs to the clinical trial submission documentation.

The RA&CA Engineer will be a key player in the Wyss Center team implementing regulatory processes according to which these medical systems (usually Class III medical systems consisting of implantable and wearable medical device components) are designed and developed, validated and brought to market. He/she will report directly to the Regulatory Affairs Manager.

Key responsibilities
In his/her position, the Regulatory & Clinical Affairs (RA&CA) Engineer will mainly:

- Support the translation of products under development to clinical applications by reviewing and compiling the technical documentation necessary for regulatory submissions
- Ensure compliance with medical device regulations and standards applicable in the USA and Europe
- Provide input to the risk management file in support of a product throughout its lifecycle
- Participate in Clinical Evaluation Report writing for class III medical devices
- Contribute to the evaluation and validation of a product to conduct feasibility studies, usability and human factors analyses, technology assessments, concept studies, benchmarking studies, or submission studies

- Develop and direct preclinical evaluation protocols, data analysis, and reports
- Support the Regulatory Affairs Manager in operational activities of projects at the Center (good practices)
- Contribute to the improvement of the Quality Management System (ISO 13485): internal audits and process deployment
- Develop subject matter expertise on specific standards
- Support Center initiatives as identified by management and in support of Quality Management Systems (QMS) and other regulatory requirements
- Support the post-market surveillance activities

The candidate should be flexible and open to providing quality solutions for neurotechnology applications in a cutting edge, multidisciplinary environment. The candidate must also be able to work independently and propose innovative approaches to quality paths suitable for active implantable medical devices.

Required qualifications and experience:

- MS in Biomedical Engineering or relevant Life Science discipline, with 5 years of experience in a similar position in the medical device industry (preferably with class III medical devices)
- Detailed understanding of the EU, Swiss and USA medical device regulations, including the MDR 2017/745/EU, MEDDEV 2.7/1 rev 4, the FDA 21 CFR Part 820 and ISO 13485 requirements
- Experience with Clinical & Regulatory Affairs in the field of Medical Devices
- Demonstrated skills in risk management (ISO 14971) and documentation structure compliant with standards and guidelines of the medical device industry (e.g. technical documentation, design history file, Investigational Device Exemption)
- Experience or knowledge in one or more of the following areas:
  - Active implantable medical devices – ISO 14708 series
  - Medical electrical devices – IEC 60601 series
  - Software as a medical device - IEC 62304
  - Medical device usability engineering - IEC 62366
  - Long-term implantable medical devices and materials
- Demonstrated ability to effectively integrate information from varied disciplines including Clinical Affairs, Engineering, Marketing and Regulatory Affairs
- Strong analytical, problem solving skills
- Comfortable working autonomously but also a team player
- Strong at taking initiative, fast learner, enthusiastic, curious
- Very high attention to details
- Good verbal and written communication ability
- Fluent in English; proficiency in French a plus

Additional skills include:

- Experience or interest in neuroscience
- Experience with CE marking, FDA clearance and approval

October 2020

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To apply, please send your **CV and cover letter** describing your qualifications, background and interest in this position to HR@wysscenter.ch. Applications received by **20th November 2020** will receive full consideration.

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