Job Description

Title: Regulatory Affairs Manager

Position: Permanent (100%)

Posted: 29th September 2021

Travel time: Up to 10 % in EU and internationally (mostly United States)

Location: Wyss Center for Bio and Neuroengineering, Campus Biotech, 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.
The 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 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 Manager** will work both independently and collaboratively at the Wyss Center to support the clinical and regulatory affairs activities in neurotechnology, neuroimaging and neurobiology projects 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.

The ideal candidate will contribute to the regulatory activities of the Wyss Center and will author the technical documentation for submission to regulatory bodies for clinical studies and/or CE marking, as part of the Wyss Center's mission to develop and translate innovative medical devices and therapies to the market.

He/she will report directly to the Center's Chief Operating Officer.

Key responsibilities

In his/her position, the Regulatory Affairs Manager will have a broad set of responsibilities which includes:

- Support the translation of products under development to human clinical trials by reviewing and compiling the technical documentation necessary for regulatory submissions in Switzerland, Europe, and United States.
- Define the regulatory strategy for Wyss Center's projects and drive the interactions with competent authorities (e.g. FDA, BfArm, Swissmedic, CCMO) and notified bodies, through regulatory processes such as pre-submissions, breakthrough devices program, De Novo, to facilitate access to future market approval processes (e.g. 510K, PMA, CE marking).
- Lead usability and human factors analyses per IEC 62366-1 for Active Implantable Devices and Software as Medical Devices.

- Support scientific and regulatory discussions with internal stakeholders within clinical, medical, regulatory, R&D and business development to drive support of the regulatory and clinical strategy, communicate evidence needs for multiple projects.
- Provide regulatory support for Risk Management per ISO 14971 activities throughout product lifecycle.
- Support clinical investigation and evaluation, literature review with the support of the Field Clinical Research Associate and Contract Research Organization.
- Perform post market surveillance, regulatory intelligence with the support of the Regulatory & Clinical Affairs Engineer.
- Mentorship of Wyss staff in various disciplines.
- Support the clinical and regulatory affairs activities in neurotechnology, neuroimaging and neurobiology projects (good practices).

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 competence and experience:

- MS in Biomedical Engineering or relevant Life Science discipline, with 6 to 8 years of experience in a similar position in the medical device industry (preferably with class III implantable medical devices).
- Experience interacting with Regulatory Authorities (such as FDA, BfArm, Swissmedic, CCMO) and Notified Bodies.
- Detailed understanding of the EU, Swiss and USA medical device regulations, including the MDR 2017/745/EU, MEDDEV 2.7/1 rev 4, FDA 21 CFR Part 820 and ISO 13485 requirements.
- Experience or knowledge in one or more of the following areas:
  - Active implantable or implantable medical devices (e.g. ISO 14708 series, EN 45502-1 series)
  - Medical device usability engineering – IEC 62366-1
  - Medical electrical equipment – IEC 60601 series
  - Software as a Medical Device – IEC 62304
  - Clinical investigation of medical devices for human subjects – ISO 14155
- Previous experience developing strategies to generate clinical evidence is preferred (Clinical Evidence Report).
- Very high attention to detail with good verbal and written communication skills.
- Strong problem-solving skills, fast learner, enthusiastic, curious, ability to mentor others.
- Fluent in English; proficiency in French a plus.

Additional competence:

- Experience or interest in neuroscience.
- End to End Project Management experience, able to manage multiple projects simultaneously.
- Statistics and statistical knowledge are a plus.

– **To apply, please send your <u>CV and cover letter</u> to** HR@wysscenter.ch**.**