



Job Description

Job title: Senior Clinical & Regulatory Affairs Engineer

Position: Permanent (100%)

Posted on: 30 June 2021

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

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 **Senior Clinical & Regulatory Affairs (CA&RA) Engineer** 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.

More specifically, the individual will contribute to the regulatory activities of the Wyss Center, and will review and provide inputs to the clinical trial submission documentation. As well 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 Senior CA&RA Engineer will be a key player inside the Wyss Center team in implementing regulatory processes according to which these medical systems (Class III medical systems consisting of implantable and external medical device components and Software As Medical Devices) are designed and developed, validated and brought to market. He/she will report directly to the Chief Operating Officer.

Key responsibilities

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

- Develop and review documents, and processes specific to the study and create study reports for clinical parts or regulatory submissions. This includes the Clinical Evaluation Plan and Report, Post Market Surveillance Plan, Literature Review and Biological evaluation results.
- Prepare clinical documentation, including Clinical Investigation Protocol, Investigation Brochure, Case Report Form and other documents required to support clinical studies.
- Set up and follow up Clinical studies with internal and external stakeholders.



- Monitor the documents related to clinical trials according to the Clinical Investigation Plan and ISO 14155.
- Lead usability and human factors analyses per IEC 62366-1 for Active Implantable Devices and Software as Medical Devices.
- Coordinate training and education to the physicians and users.
- Support clinical scientific discussions with internal stakeholders within Clinical, Medical, Regulatory, R&D and Business development to drive support of the clinical and regulatory strategy, communicate evidence needs for multiple projects.
- Provide clinical support and regulatory support for Risk Management activities throughout product lifecycle.
- Perform Post Market surveillance, Regulatory intelligence with the support of the Regulatory & Clinical Affairs Engineer.
- Mentorship of Wyss staff in various disciplines
- Support the translation of products under development to clinical applications by reviewing and compiling the technical documentation necessary for regulatory submissions.
- Support the clinical and regulatory affairs activities in neurotechnology, neuroimaging and neurobiology projects (good practices).
- Help build and maintain key relationships with competent authorities and Key Opinion Leaders (KOLs)/Advisors.

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 at least 10 years of experience in a similar position in the medical device industry (preferably with class III implantable 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 interacting with Regulatory Authorities (such as FDA, BfArm, Swissmedic, CCMO) and Notified Bodies
- Previous experience developing strategies to generate clinical evidence is strongly preferred (Clinical Evidence Report's).
- 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:
 - Clinical investigation of medical devices for human subjects. Good clinical practice – ISO 14155
 - Active implantable medical devices – ISO 14708 series
 - Medical device usability engineering – IEC 62366-1
 - Biological evaluation of medical devices – ISO 10993-1



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- Medical electrical devices – IEC 60601 series
- Software as a Medical Device – IEC 62304
- Long-term implantable medical devices and materials
- Labelling standards: ISO 15223-1, EN 1041, ISO 20417
- Demonstrated ability to effectively integrate information from varied disciplines including Clinical Affairs, Engineering, Marketing and Regulatory Affairs.
- Ability to mentor others in various disciplines.
- 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:

- Statistics and statistical knowledge are a plus
- Experience or interest in neuroscience
- Experience with CE marking, FDA clearance and approval
- End to End Project Management experience, able to manage multiple projects simultaneously

To apply, please send your **CV and cover letter** describing your qualifications, background and interest in this position to HR@wysscenter.ch no later than **30th September 2021**.