WYSS CENTER

Job Description

Job title: Quality Assurance 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 **Quality Assurance (QA) 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 work to support and maintain Quality Assurance processes, as part of the Wyss Center's mission to develop and translate to the market innovative medical devices and therapies.

> The Quality Assurance Engineer will be a key player in the Wyss Center team, implementing compliant Quality Assurance 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 Quality Assurance Manager.

Key responsibilities
In his/her position, the Quality Assurance (QA) Engineer will mainly:

- Support new product developmentand design transfer to manufacturing: establish and maintain technical documentation
- Support the development of Risk Management activities in the design and development and manufacturing phases
- Lead specific tests in relation with design verification and validation (i.e. bench testing, biocompatibility studies, stability testing, transport testing, packaging testing)
- Ensure effective design change control activities during the product life cycle
- Develop subject matter expertise on specific standards
- Collect postproduction information

- Conduct and support key supplier's audits
- Contribute to the improvement of the Quality Management System (ISO 13485): internal audits, CAPAs, process deployment
- Support the Quality Manager in the operational 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 qualifications and experience:

- MS in 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, the FDA 21 CFR Part 820 and ISO 13485 requirements
- Experience with maintenance of Quality Management Systems and Processes for 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 and/or specialization 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
- Comfortable working autonomously but also a team player
- Strong at taking initiative, fast learner, enthusiastic, curious
- Very high attention to detail
- Fluent in English; proficiency in French a plus

Additional skills include:

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

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.

October 2020