WYSS CENTER

Job Description

Job title: Quality Assurance (QA) Manager
Position: Permanent (100%)
Posted on: 16th 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) Manager** will mentor and interact with the Wyss Center community and 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 establish 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 individual will be a key player in the Wyss Center team with a leading role in setting up 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. In addition, the individual will work closely with the Center's Regulatory and Clinical experts and technical staff, as well as the Wyss Center's collaborators, towards implementing regulatory and clinical strategies necessary for global regulatory/clinical submissions.

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

- Implement and maintain QA processes and compliance activities required for Wyss Center projects, in compliance with MDR 2017/745/EU, ISO 13485 and USA 21 CFR part 820
- Train Wyss Center development teams to use, follow and work under QA Processes
- Oversee the risk management process and its related activities in Wyss Center projects
- Review and consolidate product requirements for medical device systems developed at the Wyss Center according to applicable regulations
- Actively contribute to defining medical device documentation, from user needs and applicable standards, to design verification testing, and give appropriate guidance to the development teams

- Ensure document management and control
- Define, with the Wyss Center's Regulatory Affairs Manager, quality documents in compliance with regulations, and ensure consistency of quality and regulatory strategy
- Work closely with the Wyss Center's Clinical Affairs Specialist to set up quality files suitable for submission to pre-market clinical investigation as required by Competent Authorities
- Work in collaboration with the Wyss Center's Legal team to prepare manufacturing and quality agreements with external providers and suppliers
- Work effectively in close collaboration with external providers or suppliers
- Perform quality audits of external providers or suppliers involved in Wyss Center projects

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 10 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 setting-up and maintenance of Quality Management Systems and Processes for Medical Devices
- Demonstrated skills in risk management (ISO 14971) and documentation 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
- Experience managing a small team of QA Engineers
- Excellent communication and presentation skills, including ability to communicate with academic scientists and internal clinical teams
- Comfortable working autonomously but also a team player
- Strong at taking initiative, fast learner, enthusiastic, curious
- 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

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