



Job Description

Job title: Software Quality Assurance 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 **Software 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 and support multiple projects, as part of the Wyss Center's mission to develop and translate to the market innovative medical devices and therapies.

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

Key responsibilities

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

- Responsible for quality assurance activities related to software development, verification, validation, and overall system functionality in support of the Wyss Center team, according to IEC 62304 standard.
- Develop software standard operating procedures, software test methodologies, and software verification & validation protocols and reports with the Software Development Team.
- Lead computer software validation used for the monitoring and measurement of requirements and used in the Quality Management System (AAMI TIR 36)
- Advise and support engineers on regulatory compliance for Software, Cybersecurity, Artificial Intelligence and General Data Protection Regulation.



- Support usability and human factors analyses per IEC 62366-1 for Active Implantable Devices and Software as Medical Devices.
- Support the development of Risk Management activities in the design and development phases with a strong expertise in Cybersecurity and Artificial Intelligence.
- Ensure effective design change control activities during the product life cycle.
- Conduct and support key supplier's audits
- Contribute to the set up and improvement of the Quality Management System (ISO 13485/21 CFR 820): internal audits, CAPAs, process deployment.

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 FDA software validation, Cybersecurity and Artificial Intelligence guidance's and IEC 62304 Software Lifecycle process standard requirements are required.
- 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).
- Working knowledge and experience in the following areas: Design Control, Design & Process Validation, Quality system compliance, Complaint handling, MDR/Vigilance Reporting, and CAPA process.
- Experience and/or specialization in one or more of the following areas:
 - Medical device software – IEC 62304
 - Health software General requirements for product safety – IEC 82304-1
 - Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products – UL 2900-1
 - Guidance Artificial Intelligence and Machine Learning in Software as a Medical Device
 - Application of usability engineering to medical devices - IEC 62366-1
 - Guidance on the application of ISO 14971 to medical device software – IEC TR 80002-1
 - Medical electrical devices – IEC 60601 series
 - Active implantable medical devices – ISO 14708 series
 - General Data Protection Regulation (EU) 2016/679
 - 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.



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Additional skills include:

- Experience with Jira and Bitbucket a plus
- 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 no later than **30th September 2021**.