

Job Description

Title: Project Quality Assurance Engineer

Position: Fixed term contract 3 years (100%)

Posted: 02/04/2024

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 organization that innovates and accelerates technologies and therapies to transform the lives of people with neurological and mental health disorders. The Center pursues transformational technologies in artificial intelligence, bio- and neuroengineering to restore essential neural functions and deliver precision therapeutics for people with debilitating neurological and mental health disorders.

Based at Campus Biotech in Geneva, Switzerland, the Wyss Center partners with faculty, clinicians and industry, in Switzerland and internationally, to drive innovation and maximize clinical impact.

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 achieve its mission.

About the Position

The Project 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 projects, as part of the Wyss Center's mission to develop and translate to the market innovative medical devices and therapies.

The ideal candidate is a key player in the Wyss Center team, maintaining a compliant Quality Assurance processes according to ISO 13485 and 21 CFR 820 for medical devices (ranging from Class I Software as Medical Devices up to Class III medical systems consisting of implantable and wearable medical device components). The medical devices are designed and developed and brought up to clinical trial by the Wyss Center.

They will report directly to the Center's Quality Assurance Manager.

Key responsibilities

In their position, the Project Quality Assurance (QA) Engineer will have a broad set of responsibilities which includes:

- Support assigned project(s) from development up to clinical trial: responsible to ensure effective design control activities during the product life cycle and review deliverables from the Design Control process including Design History File.
- Support assigned project(s) Risk Management activities in the design and development and manufacturing phases.





- Lead assigned project(s) Usability activities.
- Support computer software validation used for the monitoring and measurement of requirements and used in the Quality Management System.
- Support maintenance of continuous improvement of the Quality Management System (ISO 13485): internal audits, management review, nonconformance, CAPAs.
- Conduct and support key supplier's audits.
- Support the Quality Manager in the operational activities in neurotechnology, neuroimaging and neurobiology projects (good practices).

Required competence and experience:

- MS in Engineering or relevant Life Science discipline, with 8 years of experience in a similar position in the medical device industry (preferably with class III or class IIb 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:
 - Medical device software - IEC 62304
 - Application of usability engineering to medical devices – IEC 62366-1
 - Medical electrical devices – IEC 60601 series (nice to have)
 - Active implantable medical devices – ISO 14708 series (nice to have)
- 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 competence (not required, but nice to have)

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

To apply, please send your CV and cover letter to HR@wysscenter.ch no later than 21.04.2024.

