

Job Description

Title: Quality Assurance Intern

Position: Six (6) months master student internship

Posted: November 2021

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 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.

The 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 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 Wyss Center has the goal to set up a Quality Management System (QMS) according to the requirements of ISO 13485:2016. As part of this initiative, the procurement management software that controls all financial operations of the Wyss Center has to be validated and set up for daily routine work. The Intern will work within the Quality Department and in close collaboration with the Wyss Center's Finance Team to achieve this goal.

The project will offer the Intern experience with software validation, the creation of quality-relevant documentation which will be used to train other team members of the Wyss Center. It will also give him/her insights about the essential requirements of a QMS for medical devices.

The successful candidate will not only get the opportunity to shape parts of the early-stage QMS of the Wyss Center but will also work in an international, diverse and innovative environment.

The Intern will be mentored and supervised by the Wyss Center's Quality Assurance Engineer.

Key responsibilities

In his/her position, the Intern will have a broad set of responsibilities which includes:

- Customize the settings and functionalities of the procurement management software with internal requirements.
- Create the Work Instruction (WI) for the use and handling of the procurement management software.
- Update of the internal supplier approval form template to align the content of the form with the requirements of the internal electronic QMS and the procurement management software.
- Validate the procurement management software (creation of IQ/OQ/PQ protocol and corresponding reports) according to ISO/TR 80002-2 and ensure compliance with 21 CFR part 11 and cybersecurity.

- Prepare training and training materials for the team members using the procurement management software.
- Upload of relevant documents (approved supplier approval forms and related attachments) to the procurement management software.
- Prepare Key Performance Indicators (KPIs) for management review.
- Perform other quality-related tasks as needed, e.g. managing the calibration and maintenance of laboratory equipment, etc.

Required competence and experience:

- MS student/graduate in quality management, neuroscience, biomedical engineering, biology, biotechnology, chemistry, computer science or other life science related field.
- Familiarity with ISO 13485 and Medical Device Regulation (EU) 2017/745 is a plus.
- Strong affinity for quality management.
- Knowledge in software programming is a plus.
- Comfortable working autonomously but also a team player.
- Strong at taking initiative, fast learner, enthusiastic, curious.
- Very high attention to detail.
- Good verbal and written communication skills in English; verbal knowledge of French is a plus.

To apply, please send your CV and cover letter describing your qualifications, background, and interest in this position to HR@wysscenter.ch by 14th January 2022 latest.