

AOT (<u>www.aot.swiss</u>) is a Swiss Start-Up MedTech company (certified acc. to ISO 13485) dedicated to the development of robot-guided laser osteotomes for bone surgery.

We are currently looking for a

Technical Writer/Quality Engineer (m/f)

As a Technical Writer/Quality Engineer reporting to our Chief Quality Manager, you will be responsible for writing certification compliant documents, actively assisting the engineering department writing compliant documents (DMR, DHF etc.) and supporting the QA-Manager maintaining the quality management system transforming it first to ISO 13485:2016/MDD and then to the MDR.

Duties and Responsibilities:

- Establishing and editing work and test instructions, as well as design documents together with the engineering department
- Participating in the risk management process according to the QM system and regulatory requirements
- Actively participating in the QM system (EN ISO 13485:2012 + 2016, MDR)
- Actively supporting and writing technical documentation acc. to the MDD/MDR
- Support the CQM with regards to all quality and regulatory aspects

Your Skills

You have technical training and acquired "on-the -job" experience as Technical Writer and/or Quality Engineer in a MedTech environment and hence a good knowledge and understanding of:

- EN ISO 13485:2012/2016, MDD, MDR, 21 CFR 820, ISO 14971, ISO 62366-1, IEC 60601-1
- Knowledge of IEC 62304 desirable
- Knowledge of software validation desirable
- Fluent in German/English
- Nimble with MS-Office products

Further you are used to an autonomous and structured working style

Besides bringing in the ability to work in a small high-tech team, show personal responsibility and willingness to learn, the candidate should have the following characteristics:

- Amicable, hands on, open minded, good listener, solution provider
- Very good understanding for complex technical systems
- Intrinsic motivation to build and document processes

We offer the possibility to work in a young and dynamic start-up where your input makes a real difference. Interested?

Please send your job application directly to info@aot.swiss

