ARTIRIA

Quality Manager
- medical devices -

Artiria Medical is a start-up company active in the field of neurovascular technology. Artiria's objective is to establish a new standard of care to fight stroke and save lives. 13 million people suffer a stroke every year. This brain pathology often leads to severe disabilities and death. Artiria develops a cutting-edge medical device using the patient's arteries as an access route to smoothly reach the brain and locally deliver life-saving treatments.

Artiria Medical is looking for a talented & devoted **Quality Manager** to bring new standard of care to stroke patient

KEY TASKS AND RESPONSABILITIES

- Implement and maintain the Quality management System (QMS) compliant with ISO 13485, 21 CFR part 820 and applicable regulations
- Define and maintain the QMS processes and Quality Manual
- Establish and maintain the QMS procedures and deliver trainings to the team
- Manage the QMS documentation (document control - Review, approve and manage the changes)
- Act as the QA Management Representative, lead the Management Reviews, trigger action plans for QMS improvements and ensure communication with the Notified Body
- Contribute to the products' Risk Management (manage the Risk Management Files, participate to Risk Analyses)
- Define and maintain the Corrective & Preventive Actions (CAPA) processes and monitor the effective implementation
- Manage the Change Control processes and maintain an efficient workflow
- Define Quality requirements for Quality Controls, non-conformities management and on Incoming Inspections
- Be responsible for the Supplier Quality management (supplier audits, CAPA follow-up, suppliers performance evaluation)
- Act as QA Representative in the Design Transfer projects
- Define the Quality requirements for the qualification of equipment, Validation of processes, methods, and schedules.
- Contribute as an active team member to the development effort of the company
- Cultivate creativity

QUALIFICATIONS

- Bachelor's or Master's degree in science, engineering, or related field
- Minimum 4 years of working experience in the medical device industry
- Prior experience in a medical device start-up preferred, and willingness to adapt to a small company environment
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- Knowledge of the Medical Device industry standards : ISO 13485, 21 CFR part 820, ISO 14971 and EU Medical Device Regulation 2017/745
- Quality focused mindset as part of best business practices and not just compliance
- Drive to use quality as an accelerator towards commercialisation of medical devices
- Experience in implementation of full QMS is a plus
- Experience of integrated, electronic Quality Management Systems (eQMS) is a plus
- Background in endovascular technology is a plus
- Independence and organizational skills to achieve results efficiently
- Good team player
- Languages: English and French, written and spoken

WE OFFER

- A job that makes sense! Contribute to a product that can save people's lives
- Become part of a young and creative Swiss Medtech Startup

- Work with an experienced team of entrepreneurs, scientists and Medtech experts
- Grow professionally with the company
- Attractive start-up environment
- Permanent position

STARTING DATE: October 2020

LOCATION: Geneva, Switzerland

APPLICATIONS: jobs@artiria-medical.com