Quality & Regulatory Affairs Manager (SaMD / Neurotech)

Geneva, Switzerland | Full-time | Start: as soon as possible

Mind Metrix
Spin-off | ETH zürich

At MindMetrix, we are building the next generation of digital therapeutics for mental health care. By combining neuroscience with advanced digital tools, we aim to transform how mental disorders are detected, treated, and prevented. Having evolved from a consumer sports-based product, we are now entering the clinical space and building a team who wants to bring this vision into practice with us.

Job Description:

We are looking for a Quality & Regulatory Affairs Manager. You will build and manage our regulatory and quality systems for Software as a Medical Device (SaMD) development and clinical studies in collaboration with experienced regulatory and quality advisors. You will translate regulatory strategy into practical processes and documentation while driving the day-to-day execution of our quality management system. You will work closely with experienced regulatory and quality advisors as well as company leadership to implement and operationalise our regulatory strategy and quality systems.

This is a hands-on operational role at an early-stage neurotech startup, requiring strong operational execution, ownership, and the ability to build and manage processes from scratch in a collaborative environment. It offers the opportunity to work closely with experienced regulatory and quality professionals while gradually taking increasing ownership as the company grows.

Responsibilities:

- Foster a quality culture based on responsibility, transparency, and benevolence, suited to a small, highly engaged team.
- Work closely with management and third-party stakeholders to ensure alignment between strategy and execution.
- Establish, implement, and maintain a lean, risk-based Quality Management System in accordance with ISO 13485, EU MDR, Swiss MeDO and FDA QMSR.
- Act as Management Representative and support PRRC activities under EU MDR requirements, in collaboration with internal and external regulatory experts.
- Own and implement risk management activities in accordance with ISO 14971, including hazard identification, risk analysis, risk control, and benefit-risk justification.
- Support the team in embedding quality-by-design principles within agile and/or hybrid development workflows.
- Prepare the organisation for certification audits (ISO 13485), notified body interactions, and potential Competent Authorities inspections.
- Translate regulatory strategy into practical processes such as preparing technical documentation and drafting SOPs.
- Provide regulatory and quality oversight for medical device development activities across defined regulatory pathways.

- Ensure the compliance of medical device technical documentation with the applicable regulatory requirements and proactively address compliance issues to uphold regulatory standards.
- Support and manage direct interactions with relevant National Competent Authorities in the EU, CH and the US and, where applicable, notified bodies.

Requirements:

- MSc in Biomedical Engineering or a related Life Science discipline, with at least 3 years of experience in regulatory/quality affairs within the medical device industry (PhD is a plus).
- Experience with SaMD is a requirement.
- Good understanding of the EU, Swiss and US medical device regulations, guidance and standards, including the MDR (EU) 2017/745, the FDA 21 CFR Part 820 and ISO 13485 requirements.
- Experience interacting with National Competent Authorities (e.g. Swissmedic, FDA) and Notified Bodies.
- Hands-on experience with implementing or working within a QMS.
- Familiarity with relevant standards (ISO 13485, ISO 14971, IEC 62304, IEC 62366-1 and IEC 81001 5 1)
- Strong organisational and communication skills, with the ability to work across disciplines.
- Fluency in English and a valid work permit for Switzerland is required (we are not able to offer permit sponsorship at this time). French is a plus.

What we offer:

- Full-time position, starting as soon as possible.
- Flexible working hours and hybrid set-up, with on-site workdays in Geneva.
- Competitive salary CHF 100'000 – 130'000, 5 weeks of vacation, opportunity for long-term career advancement and equity participation.
- A collaborative, interdisciplinary team with backgrounds in neuroscience, tech, and business.
- The chance to shape an early-stage clinical product with direct patient impact.
- An open, supportive culture that values initiative, curiosity, and passion.

About MindMetrix

MindMetrix is a spin-off from ETH Zurich, where we developed a novel pupil-based neurofeedback method that enables users to actively regulate their brain's arousal level. Our first product, myflow, has been applied in elite sports, giving athletes immediate feedback on their mental state and helping them perform at their best. Building on this foundation, we are now expanding into the clinical field. From our new base in Geneva, we are working with leading experts in neuroscience to develop applications that support patients with anxiety and other mental health disorders. Our goal is to create accessible, science-based tools that make a difference in people's lives.

Application:

You are interested? Send us your CV and shortly explain what you'd expect from this opportunity at job@mindmetrix.ch. And keep it real. We want your story, not a flawless AI draft.

We look forward to hearing from you!

Geneva, 01.06.26