mobile Health is a start-up company that develops digital applications for cancer patients. With our applications, we accompany them through the difficult time of cancer therapy and improve communication with the treatment team.

To strengthen our team in Zurich we are looking for an immediate or by appointment

(Junior) Manager of Quality and Regulatory affairs (80-100%)

The Junior Manager of Quality and Regulatory affairs will be responsible for Quality and Regulatory affairs within mobile Health; planning, development, review, verification, validation and risk management activities associated with medical device software development projects. This will include supporting all product design activities and ensuring proper execution of the development process as well as the resulting documentation, product submissions and registrations (e.g. Swissmedic, DiGA).

This position provides guidance to development teams on applicable regulatory and statutory process and product requirements. Additional responsibilities include the development of processes and process improvement projects.

This role requires technical and regulatory (EU-MDR) knowledge with an emphasis on Software as a Medical Device and software systems.

Responsibilities:

- Liaise with health authorities and notified bodies on product-related regulatory issues; Schedule, participate in, and prepare briefing documents for communicating with health authorities and notified bodies
- Develop regulatory strategies to ensure the most efficient regulatory review pathway;
- Ensure development projects meet defined development process requirements of EN/ISO 13485:2016 and MDR 2017/745.
- Ensure software development is compliant with IEC 63204:2015 standard.
- Support design verification and validation testing including providing guidance in developing and validating test methods, reviewing, and approving test records.
- Drive risk management activities for projects in compliance with ISO 14971:2019.
- Ensure timely completion of all Quality Assurance deliverables to support the design and development projects.
- Manage developmental design change process for each project's specifications.
- Manage document control of each project team’s development documentation
- Ensure the quality of all design and development documents and records, so that they readily support regulatory submissions.
- Organization and compilation of project’s/product’s design history record set
- Manage internal and external audits as required.
- Manage Quality Management System development and updates as required.
- Drive Quality functions e.g. CAPA and Complaint management as required.

- Manage preparation of submissions; ensure consistency, quality, and completeness
- Provide leadership and guidance to the organization regarding compliance and inspection readiness
- Ensure effective ongoing review of product design and/or changes
- Oversee regulatory vigilance and post-market reporting.
- Support mobile Health's 3rd party software developers which require regulatory expertise as needed

Qualifications:
- 2+ years of Software as a Medical Device or relevant quality experience.
- Thorough understanding of MDR, ISO 13485, 14971, 27001, IEC 62304 requirements
- Experience with EU Health Authorities or Notified Body required.
- Advanced analytical and problem-solving skills.
- Strong attention to detail
- An approachable individual who provides a high level of teamwork.
- Outstanding communication and interpersonal skills
- Ability to effectively organize and prioritize tasks
- Experience with project management tools such as Jira, Confluence and MS Teams.
- Familiar with Q&A (Quality and Assurance) cases and Software Testing Life Cycles (STLC)
- Excited to learn in a fast-paced environment

We offer:
- Responsible and independent work in a successful startup environment
- Open and familiar working atmosphere in our young and highly motivated team
- Meaningful product with social added value
- Flexible working hours and home office options
- Workplace in Zurich

Contact:
We are looking forward to receiving your application dossier in one (1) pdf file directed to:
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