The Company

We believe new digital technologies have the potential to enable us to do what we do today in even better ways tomorrow. How can we unlock the potential of such technologies to benefit society and create sustainable value?

Leitwert is streamlined on market pull: when solving real problems with and for our clients we create simple and modular solutions. By doing so we are bootstrapping a digital technology company for the 21st century, always keeping in mind that every development and every innovation must ultimately create value by reducing cost or increasing efficiency.

In a stimulating environment, we realize technologically sophisticated projects. Leitwert originates from a robotics project at the ASL (Autonomous Systems Lab www.asl.ethz.ch). We constantly explore new technologies to increase our know-how, widen our horizons and expand our expertise in electronics, asynchronous programming and product development into new fields such as augmented reality or computer vision.

Our projects range from wearable devices for vital sign monitoring (consumer, professional sports, medical research) to sensing systems (remote monitoring of pharma production processes, smart metering, flight controllers), algorithm development (machine learning, image processing, 3D image mapping, pattern detection), firmware (from consumer products to safety critical applications (medical) - see also www.ConcRTOS.io) secure and encrypted firmware delivery and device management (https://dms.leitwert.ch https://orbit.leitwert.ch https://clinics.leitwert.ch) to web apps (e.g. for energy data management in retail or data collection in agriculture). We are also active in emerging fields like augmented reality applications.

With our solutions for connected products we master the key competencies to collect, store and analyse large amounts of data – with growing focus into regulated market segments.

Grow with us and become a driving part of the team as

Regulatory Affairs Manager - Medical Device & SW (f/m)

Objective

You will be responsible for setting up Leitwert's regulatory affairs activities within a Medical Device/"Software as a Service" environment from scratch on! You are our driving force & functional knowledge base for setting up, planning, mediation, execution and delivery of our company wide Regulatory Affairs Systems & Certifications. You assure compliance with applicable medical device regulations per jurisdiction, guidance and given standards and drive the creation and maintenance of our regulatory reputation. Your task: Get us certified!

Main responsibilities:

- Set-up & maintain regulatory files management from scratch on. Create and update regulatory authorizations, such as i.e. ISO Certification and CE dossiers for CH/EU/US certifications etc. Assure that appropriate maintenance of registrations occurs including initial certifications, renewals, site registrations, supplements for changes and annual reports.
- Lead & prepare response to regulatory authorities within assigned timelines.
- Assess medical devices & SW as a Services related incidents/complaints for medical device reporting requirements. Compile and submit reportable events to relevant regulatory authorities in timely manner. Handle recalls and field actions, if required.
- Write, analyse, and edit technical documents to support country- specific regulatory submissions and compile submissions in a format consistent with applicable guidance documents, including investigational device submissions in Switzerland, Europe, USA. Work with other departments (Commercial, Technics) and communicate the submission requirements when documents are needed for regulatory submission.
- Stay abreast of regulatory procedures and changes in regulatory climate.
- Review and create product promotional material for compliance with applicable regulations and technical standards.

- Support external regulatory agency audits, providing regulatory input to minimize potential for findings of non-compliance.
- Assist in preparing clinical trial site ethics review board applications for investigational device trials. Prepare interim or final reports for trial site ethics boards as required
- Other duties as assigned, you will report directly into the Executive Team.

Your profile

- Min. bachelor's degree or country equivalent in Medical Engineering or Science or related scientific disciplines, or equivalent. Higher degree/PhD will be an advantage
- Minimum of >5 years regulatory or equivalent experience within a medical device or pharmaceutical company, CRO, SW as a Service-company or similar organization
- Scientific knowledge, you must be able to digest complex data while keeping the big picture through good analytical skills
- Excellent written and verbal communication & negotiation skills with the ability to listen, articulate and advocate on senior management level
- Proactive, high performance, result oriented and manage projects with ethical integrity
- Manage multiple projects and deadlines across a variety of external/internal stakeholders
- Ability to early identify, escalate & solve compliance risks
- Demonstrate both creative and critical thinking skills
- experience in med-tech with specific focus on SW as a Service would be a real distinctive advantage, but not a pre-condition
- operational value realization professional with positive, open and communicative personality, clearly a cross functional team player, proactive character
- excellent presentation & influencing abilities with local authorities, executives, customers
- you bring know-how of IoT based software, tools & scalable medical devices (wearables)
- you feel comfortable in a start-up company culture and prepared to contribute to shaping it further while loving the full functional responsibility. As a Start-up Multitalent you are:
    - hungry to leave your comfort zone,
    - fast learner: able to analyse a situation and learn what is required to master it,
    - hands-on working style,
    - structured, proactive and taking responsibility
    - you love challenges and thrive in a challenging environment
- excellent english and german skills are a prerequisite

What we offer

- diversified work with lots of exposure to R&D, Medical Device & other IoT Industry clients (high-tech companies from CH, EU and the Silicon Valley)
- highly motivated, dynamic team and the opportunity to build up our team with us, to actively shape our company culture, and to invent the world of tomorrow with us.
- working location: Zürich
- flexible working hours

Are you a team player with the urge to deliver first-rate performance? In that case, we would be delighted to have you on board.

Miro Käch is looking forward for your complete application at jobs@leitwert.ch (motivation letter, CV, employer references, degrees including grades).