zurich43

TI Solutions

TI Solutions AG

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TI Solutions AG, a recently founded and well-funded startup company is currently seeking applicants for the post as

Senior Quality & Regulatory Affairs Specialist

TI Solutions AG develops high-quality and flexible stimulation devices and treatment planning tools for temporal interference (TI) research and clinical applications. The company is closely associated with the Zurich43 alliance consisting of the Foundation for Research on Information Technologies in Society (IT'IS), Schmid & Partner Engineering AG (SPEAG) and ZMT Zurich MedTech AG. Z43's dedicated mission is to expand the knowledge and technology for the (i) characterization, optimization, and application of the electromagnetic near-field and (ii) predictive modelling of interactions between physical agents and physiology in complex anatomies.

Your challenges:

- Implementation and continuous improvement of the Quality Management System (QMS)
- Drive and monitor compliance of our QMS processes through close collaboration with production and advise on product development, manufacturing changes, and technical labeling in terms of interpretation of the appropriate regulations
- Responsibility that quality systems (e.g., deviation system, change control system) are consistently followed
- Provide a timely handling of all quality relevant topics and compliance with current EU and FDA regulations
- Escalate any issues which may impact the compliance status or product quality of our products
- Liaise with notified bodies and authorities to support the implementation of the global regulatory strategy and expedite regulatory approvals
- Support post-market surveillance activities and ensure compliance with post-market approval requirements
- Support of clinical trial submissions

Your strengths:

- University or technical college degree (Bachelor, Master or PhD) in Engineering, Life Sciences or another relevant discipline
- Experience in QA environment within Medical Device, Pharma or Biotech industry
- Profound knowledge of European and US regulations, guidelines and standards such as ISO 13485, EC Regulation 2017/745, FDA 21CFR part 11, ISO 9001, ICH etc.
- Working knowledge of QMS ISO 13485 regulations; deep understanding of medical device manufacturing process, change control and training process requirements
- Ability to collect data, analyze situations and propose optimal process solutions to meet both compliance and business requirements
- High level of quality mindset for all tasks and strong analytical thinking
- Analytical and structured working style; strong attention to detail
- Ability to effectively work as part of a multidisciplinary, international team
- Strong written and verbal communication skills in English

Our offer:

- Stimulating environment for innovation at the forefront of our research areas and key technologies
- State-of-the-art laboratories, high-performance computing clusters, and production facilities

- Vibrant and open company culture thanks to a diverse and creative mix of people from across the globe with various backgrounds in physics, electronics, mathematics, biology, etc.
- Colleagues who are smart, competent, and passionate about valuable, cutting-edge work and who strive to meet high ethical standards

Applications will be accepted until the position is filled. Direct applications are preferred; applications submitted via recruitment agencies are discouraged. Please note that incomplete applications will be disregarded.

Please send your application documents (in English) consisting of motivational letter, detailed CV (max 2 pages), diplomas, transcripts (with grades), work certificates and/or reference letters (if available) to:
Zurich43, Yvonne Maeder, Zeughausstrasse 43, 8004 Zurich, Switzerland, Phone: +41 44 245 96 96, jobs@z43.swiss

Informal enquiries are welcome and should be directed to Dr. Sabine Regel (regel@temporalinterference.com).