

Regulatory Officer II

Description

Sword Health is on a mission to free two billion people from pain as the world's first and only end-to-end platform to predict, prevent and treat pain. Delivering a 62% reduction in pain and a 60% reduction in surgery intent, at Sword, we are using technology to save millions for our 2,500+ enterprise clients across three continents. Today, we hold the majority of industry patents, win 70% of competitive evaluations, and have raised more than \$300 million from top venture firms like Founders Fund, General Catalyst, and Khosla Ventures. Recognized as a Forbes Best Startup Employer in 2023, this award highlights our focus on being a destination for the best and brightest talent. Not only have we experienced unprecedented growth since our market debut in 2020, but we've also created a remarkable mission and value-driven environment that is loved by our growing team. With a recent valuation of \$2 billion, we are in a phase of hyper growth and expansion, and we're looking for individuals with passion, commitment, and energy to help us scale our impact. Joining Sword Health means committing to a set of core values, chief amongst them to "do it for the patients" every day, and to always "deliver more than expected" on behalf of our members and clients. This is an opportunity for you to make a significant difference on a massive scale as you work alongside 800+ (and growing!) talented colleagues, spanning two continents. Your charge? To help us build a pain-free world, powered by technology, enhanced by people accessible to all.

Introduction: We are seeking a dedicated Regulatory Affairs Officer with at least 2-3 years of experience in the medical device industry with a good understanding of medical device regulations with focus on EU and US to join our QARA team. The successful candidate will be primarily responsible for maintaining and updating technical file documentation to ensure compliance with international regulations and standards. This role is critical in supporting Sword Health's ongoing efforts to meet stringent regulatory requirements and to facilitate the successful marketing and distribution of our medical devices.

What you'll be doing : Update and maintain technical documentation for medical devices in accordance with applicable regulatory requirements, including but not limited to the EU MDR (Medical Device Regulation), FDA guidelines, and other global regulatory frameworks. Collaborate with cross-functional teams, including R&D, Quality Assurance, and Clinical Affairs, to gather necessary documentation and data. Ensure all technical files are complete, current, and in compliance with relevant laws and standards. Support the quality & regulatory department (QARA), in audits and regulatory inspections. Provide regulatory advice and guidance to project teams on regulatory requirements, especially related to changes in product design, labeling, or manufacturing processes. Monitor regulatory developments within the medical device field and advise on impact and necessary actions.

What you need to have: Previous experience (2-3 years), in the Medical Device industry (or other regulated industry such as Pharma, IVD). Bachelor's degree in a technical, scientific, engineering or related field is preferred. Good working knowledge of regulations and industry standards for US, CA and EU markets, such as ISO13485, EU MDR, 21 CFR 820, etc.. Proven experience in preparing and maintaining technical documents and technical files, including experience in Change Control. Strong attention to detail and the ability to manage multiple projects under tight deadlines. Excellent communication, interpersonal and organizational skills and proficiency in English. Highly dynamic, motivated and proactive. Team player with ability to successfully interact with representatives from a variety of disciplines within and external to Sword Health. What we will love to see : Previous experience with NB submissions is an advantage. Previous experience in supporting the Design Control process is an advantage.

To ensure you feel good solving a big Human problem, we offer: A stimulating, fast-paced environment with

Hiring organization

Sword Health

Job Location

PT

Base Salary

\$ 85000 - \$ 117500

Date posted

May 8, 2024

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lots of room for creativityA bright future at a promising high-tech startup companyCareer development and growth, with a competitive salaryThe opportunity to work with a talented team and to add real value to an innovative solution with the potential to change the future of healthcareA stimulating environment with room for creativityA flexible environment where you can control your hours (remotely) with unlimited vacationAccess to our health and well-being program (digital therapist sessions)Remote or Hybrid work policy.Please mention the word ****ENCOURAGEMENT**** and tag RNTluMzYuMjAxLjEyOQ== when applying to show you read the job post completely (#RNTluMzYuMjAxLjEyOQ==). This is a beta feature to avoid spam applicants. Companies can search these words to find applicants that read this and see they're human.

Contacts

Job listing via RemoteOK.com