REGULATORY AFFAIRS SPECIALIST

Company Description

Looking for a new challenge? Cyber Surgery is a Spanish medical robotics company, founded in 2017 and located in San Sebastián - Donostia (Basque Country). After successfully completing clinical trials on patients this year, our robot is the 1st of its kind, developed in Spain to reach this important milestone, and we are so proud of it that now we go further with even more ambitious projects! At Cyber Surgery every day you'll work to improve patient's quality of life. You'll design and develop robotic solutions that will transform robotic surgery. Through the power of many bright and curious minds we're committed to solve some of the spinal surgery's most complex challenges. That's why we value collaboration, bringing talented people together to share ideas and create disruptive solutions.

Information

Deadline: 2023-09-30
Category: Business
Province: Gipuzkoa
Country: Basque Country
City: Donostia

Company

Cyber Surgery

Main functions, requisites & benefits

Main functions

We are seeking an experienced Regulatory Affairs Specialist to lead medical device registrations in the company.
Belonging to QA&RA department, you will lead device registrations across global markets, assuring the target market's registration requirements.
You will be responsible for compiling all the necessary documentation for the regulatory submission and submitting it to the appropriate regulatory body to obtain registration and approval. Managing FDA premarket notifications and submissions. Objectives: Managing regulatory documentation. Managing product bench testing for submissions. Drafting test protocols/development plans and reports. Ensuring compliance with federal laws and applicable standards. Ensuring compliance with Title 21 CFR Part 820 in the company and subcontractors. Establishing communications with FDA. Managing responses to warning letters.

Requisites

Minimum qualifications Bachelors degree in Pharmacy, Chemistry, Biology, Engineering, or other Life Science field. 3+ years of professional experience in Regulatory Affairs in United States. Preferred qualifications Experience and in-depth knowledge of American Medical Device regulation (CFR Title 21). Experience with FDA processes (premarket submissions). Preferable with Class II or Class III medical devices. Advanced written and oral English skills. Excellent organizational, prioritization, and problem-solving skills. Excellent project management skills. Ability to effectively manage multiple tasks/projects with varying deadlines and requirements. Excellent MS Office Software (Word, Excel, PowerPoint) skills. Excellent technical and report writing skills. Ability to effectively work both in a team situation and individually with minimal supervision.

Benefits

Here are some good reasons to join us: Being a part of cutting-edge research and development team making better quality surgeries for patients. We are a growing fast company, made of passionate people about health and robotics. Joining a young, dynamic and innovative company in the field of medical devices in one of the best cities in the world: Donostia - San Sebastian! 1st Spanish company that achieves complete clinical trials in humans and getting ready to launch product to the market. Personal and professional growth through seminars and trainings in different fields. Multidisciplinary work team. Positive work enviroment! Great conditions & benefits which include flexibility for a balanced work-life: health insurance, retirement plan benefits, flexible scheduling, teleworking...