Position: **Regulatory Affairs Specialist**

Publication date: 19/12/2023

Private Foundation Món Clínic Barcelona

We are a private, newly created, and non-profit Foundation, linked to the Hospital Clinic de Barcelona, whose mission is to strengthen public health and improve the quality of life of citizens. To respond to our founding goals, we have an academic CRO for conducting clinical studies, initiated by the pharmaceutical and health technologies industry or by researchers, both in the field of medicine and medical devices, offering a comprehensive portfolio of services to meet the needs of our customers.

We are looking for a talented and motivated Regulatory Affairs Specialist to join our team. As a Regulatory Affairs Specialist you will be responsible for the day-to-day implementation and monitoring regulatory and certification activities to ensure compliance with all relevant regulations.

Major Responsibilities:

- Define regulatory and certification strategy and roadmap for customers, including preparation for upcoming clinical studies.
- Prepare clinical development plans, which integrate clinical and regulatory strategies.
- Preparation and management of product files in regulatory submissions with input from external experts to obtain clearance for commercialization in Europe of medical devices.
- Preparation for meetings with regulatory authorities, including preparation of background materials, logistical organization and preparation of meeting minutes.
- Set up and maintain contacts with regulatory authorities.
- Stay current with changes in regulatory requirements.
- Identification, compilation and approval of Regulatory SOP's.

Skills, Experiences and qualifications required for the job:

- BS/MS degree or similar in human health related discipline
- Experience in drug and/or medical devices development and international regulatory processes
- Expertise on Quality, Nonclinical and/or Clinical drug/medical device development
- Excellent written and verbal communication skills in English.
- Work effectively and productively
- Strong interpersonal, communication and presentation skills
- Very high sense of integrity and confidentiality
- Demonstrable experience in regulatory procedures at the EMA and/or FDA and/or any of the Member States' regulatory agencies is a plus for drugs and at Notified Bodies for medical devices

Working conditions:

- Full time position
- Offices located in the center of Barcelona.
- Teleworking possibility.
- Salary to be determined.
- Starting date of the contract: February 2024.

If you are interested in this offer, please send your CV to the following email:
amiralles@fundaciomonclinicbarcelona.cat