Regulatory Affairs Specialist Jr. (Medical Device)

We are **Sycai Medical**! A young MedTech startup focused on increasing the detection of early-stage cancer and improving patient's life quality applying AI-based algorithms to medical imaging tests. Our first product helps radiologists to detect and classify pancreatic cystic lesions on CT scans and MRI. It also automatizes the report generation and predicts the probability of each lesion to evolve to pancreatic cancer, the 4th leading cause of death by cancer in Europe with an average survival time from diagnosis of 5 months.

Sycai is engaged in an active phase of development and hiring young talent to help us grow together! If this sounds like an exciting opportunity, we want to hear from you!

We are currently looking for a focused, autonomous, and ambitious Regulatory Affairs Specialist who's also a team player. In this position you will work on document preparation, information management, file maintenance, and coordination of tasks across multiple departments. Part of your strategic directive will be to achieve a balance between regulatory concerns, technology, marketing objectives, compliance, time to market, and costs. For this reason, communication with employees at all levels within the organization is extremely important!

As a Regulatory Affairs Specialist you will need to understand all aspects of product development, including research, clinical trials, manufacturing practices, regulations, and approval processes. Don't worry! You don't need to bring all this knowledge with you, we can learn together!

What you will do:

- Explain regulations, policies, or procedures. Regulatory roadmaps & feasibility assessments.
- Classification Strategy & Customized Development Plans.
- Country Specific Regulatory Support
- Assistance with local Competent Authorities communication
- Product registration
- Other local requirements
- MD EU Technical File revision, compilation, and maintenance (General Safety and Performance Requirements, Risk Analysis, Clinical Evaluation Reports, Instructions for use and Labelling, etc.)
- Conformity Assessment – Medical Device EU Certification Procedure assistance.
- Quality Management System (QMS) design and implementation based on ISO 13485.
- Maintain data in information systems or databases.
- Advise others on regulatory and compliance matters.
- Evaluate applicable laws and regulations to determine impact on company activities.
- Provide technical review of data or reports.
- Coordinate regulatory documentation activities.
- Identify and interpret relevant regulatory guidelines.

Who you are:

- You have a degree in the disciplines of life science, clinical science, public health or similar.
- Background and experience in regulatory procedures.
- Knowledge of how the Regulatory Department contributes to Business Development.
- Indispensable fluent English, spoken and written.
- Combination of leadership with strategic vision.
- With technical knowledge and records.
- Organized and resolutive.
- Agile and able to adapt to changes.

What do we offer:

- Young, open innovative and dynamic environment in the center of Barcelona.
- Flexible work-life balance, balancing working hours and home office.
- Growing together: we are an early-stage company with a multidisciplinary team.
- Equal employment opportunity: we proudly pursue a diverse workforce and we do not make any hiring or employment decisions that could be discriminatory in any way.
- First salary 18.000 – 23.000€