Quality Manager

Company

QYNAPSE is a medical technology company that provides a cloud-based platform for the diagnosis, prediction of clinical evolution and measurement of drug efficacy for central nervous system diseases (including Alzheimer's, Parkinson's and Multiple Sclerosis).

We combine leading edge quantitative imaging and artificial intelligence to support the targeting of clinical trials, drug development and personalized patient care.

The company is headquartered in Paris. It is ISO 13485:2016 – certified, and its first medical device is CE-marked and awaiting FDA clearance.

Job responsibilities & Mission

We are looking for a Quality manager to **drive the regulatory strategy for the company and its medical devices**.

Reporting to the CEO, your missions will be the following:

- Managing the Quality Management System (ISO 13485:2016):
  - Assuming the role of management representative for the regulatory authorities,
  - Writing and updating documents necessary to the Quality Management,
  - Handling non-conformities,
  - Implementing corrective action plans,
  - Training the team members to the use of the Quality Management System,
  - Planning and organizing audits (internal and certification).
- Ensuring that regulatory requirements are fulfilled for the medical devices designed by the company:
  - Implementing regulatory plans and strategies for the medical devices,
  - Handling the implementation of the technical file documents in agreement with international regulatory requirements,
  - Participating in the medical devices' verification tests,
  - Performing a continuous surveillance of the standards evolution, worldwide,
  - Communicating with relevant health autorities.

This position will include close interactions with the Data Science, Imaging, Development, and Clinical research teams at Qynapse.

Profile

- **Master's degree**, with a focus on Quality Management and regulatory pathways
- At least **2 years of experience** in the implementation and/or follow-up of regulatory affairs related to medical devices
- Efficient, focused, organized & autonomous

Skills

- **Required**
  - Experience with applicable European standards: ISO 13485:2016, EU 2017/745
  - Experience with the regulatory pathway for FDA clearance
  - Fluent in English
- **Plus at least one of the following:**
  - Experience with medical devices software
  - Experience with neuro-imaging
  - Experience with international regulatory requirements
  - Experience with the General Data Protection Regulation
  - Experience with data science and predictive algorithms

Contract and remuneration

- Full-time position starting as soon as possible
- Remuneration depending on experience

Location

130 rue de Lourmel, 75015 Paris

Application

Apply by email at careers@qynapse.com, by attaching a resume or a LinkedIn profile. Please feel free to attach other documents that could support your application.