



AVATAR MEDICAL

Regulatory / Quality Trainee

Paris, France + Partially/Totally Remote

AVATAR MEDICAL SAS is an exciting new MedTech start-up that radically enhances the manner in which surgeons prepare their surgeries.

Based on technology developed at the **Institut Pasteur** and **Institut Curie**, **AVATAR MEDICAL** uses advanced image processing algorithms coupled with virtual reality (VR) to transform medical images (e.g. CT-scans, MRI) into lifelike patient avatars. This vehicle grants surgeons an excellent understanding of their patients' pathology via an immersive and interactive VR experience. Our technology is meant to facilitate communication between radiologists and surgeons, allowing a more efficient and rapid surgical planning. Our technology has been recognized with numerous scientific and medical journal publications and **AVATAR MEDICAL** is a laureate of the prestigious BPI i-Lab and I-Nov Competition for innovative startup companies.

AVATAR MEDICAL's leadership team consists of passionate French and American co-founders with proven experience in tech entrepreneurship, sales, marketing and scientific research. Our technology, being commercialized between France and the USA, is developed by a talented team of physicists and software engineers who work closely with the Decision & Bayesian Computation Laboratory at Institut Pasteur (member of the Paris Artificial Intelligence Research Institute, PRAIRIE) and the Breast Cancer, Gynecologic Cancer and Reconstructive Surgery Unity at the Institut Curie. Created in 2020, one key objective of the start-up is to transform this innovative technology into a medical product, recognized by appropriate FDA and CE certifications.

In this perspective, we are looking for a Regulatory / quality trainee to join the Quality and Regulatory Affairs (QARA) team. The successful candidate will participate in the updating of the ISO 13485 Quality Management System documentation (Medical Device standard) in preparation for certification activities and the development of technical files for the marketing of Medical Device software. He/she will report to the Quality Regulatory Manager. This position is the perfect opportunity to discover and take part in the full QARA process and will lead you directly to a job with responsibilities at **AVATAR MEDICAL**.

Mission

- Meet standards requirements of the ISO 13485, ISO 14971, IEC 62304 and regulation 2017/745.
- Contribute to risk analysis for medical devices: knowledge of the ISO 14971 standard.
- Actively participate in maintaining the quality management system according to the ISO 13485 standard.
- Contribute to the compliance of the design/development process with the delivery of our products.
- Participate in the preparation of quality indicator reports in preparation for process and management reviews.
- Contribute to Technical Documentation to submit to Notified Bodies and FDA (Clinical Evaluation, Usability Engineering Summative Evaluation, GSPR, ...)
- Contribute to post-production monitoring of products post-market (non-compliance, bugs, changes).
- Contribute to normative and regulatory monitoring.

**Required Qualifications:**

- Student in Engineering School / Quality and Regulatory Master's degree, looking for end-of-studies internship.
- Knowledge of quality standards and management by the process.
- Autonomous and organized, able to work in a transverse network and a team.
- Good analytical and synthesis skills.
- Perfect writing skills in English.
- Take initiative, proactive.
- Ability to listen and good adaptability within the framework for implementation of quality approach.
- Capable of adapting to new software tools rapidly (we use Google Suite, and Confluence).

Nice-to-Have Qualifications

- ISO13485 knowledge (Quality Management of a medical device) and IEC62304 (Software Life cycle) would be a plus and will help to quickly understand the characteristics and challenges of the startup
- Bilingual French/English.

Contract

6 months internship starting in 2024

(Possibility to join our growing team at the end of the traineeship, if everything goes well!)

Location

In Parisante Campus 10 rue d'Oradour Sur Glane 75015 Paris

OR in our new offices in Saint Malo

Partial remote working possible

Contact

Please contact jobs@avatarmedical.ai with your

- CV
- Motivation Letter
- References