QARA Engineer

Tribun Health, AI-Powered Pathology - Paris, France (Hybrid)

Apply on LinkedIn or send your application to jrat@tribun.health Tribun Health has been the leader in solutions for clinical decision making using digital pathology for over 15 years. Our mission ? Accelerate diagnosis, improve patient care so that cancer is no longer a fatal disease.

We pioneer advanced artificial intelligence technology that automatically extracts the most relevant data from pathology slides, accelerates and improves image quantification for diagnosis, prognosis and analysis biomarkers. Our products have been developed with the assistance and experience of pathologists from prestigious private, public and academic institutions around the world.

As a world leader, we are keen to meet the expectations of our customers (public hospitals, private laboratories and the pharmaceutical industry). Customer satisfaction, innovation, patient impact and teamwork are at the heart of our success. Tribun Health has also won the prestigious "Best in KLAS" customer experience award for digital pathology for 2022.

Tribun Health is accelerating its development and recruiting new talent. If you want to take up new challenges, join our QARA team and participate in the various quality issues of a structure in full international expansion. Reporting to the QARA Director, within a committed team, you take full part in Tribun Health's development projects. Your skills and your state of mind are the actors of the success of the company.

Your main tasks will be:

- Contribute to the maintenance and development of the QMS in accordance with ISO 13485, 21 CFR Part 820 and regulation 2017/746,
- Contribute to compliance with Cybersecurity requirements (ISO 27001, etc.),
- Contribute to the implementation, maintenance and efficiency of the eQMS in conjunction with the process pilots,
- For the medical devices for which you are responsible:
- Develop and maintain with the R&D team a technical file compatible with the various regulatory registrations (FDA, CE, Health Canada, ...),
- Participate in product risk management,
- Ensure compliance with regulatory requirements and ensure compliance,
- Ensure post-marketing activities,
- Participate in the development of clinical assessments,
- Participate in the creation of regulatory files for CE certification (Europe), FDA (USA), etc.
- Be proactive on quality and regulatory aspects,
- Regulatory monitoring,
- Contribute to the analysis and communication within the company of the regulatory requirements relating to the medical devices developed,
- Contribute to the implementation and maintenance of measures relating to the protection of personal data, according to the regulations in force in the geographical area concerned,
- Participate in employee training on quality and regulatory requirements

In order to carry out these missions, we are looking for the following skills:

- Real ability to work in a team and possess good interpersonal skills;
- Ease of adaptation, start-up mindset;
- Good analytical and problem solving skills;
- Faculty of communication and expression, both written and oral, in English and French;
- Mastery of the ISO 13485 standard;
- Mastery of the risk management process (ISO 14971, ISO/TR 24971, IEC 62366-1);
- Mastery of directives relating to the life cycle of medical device software (IEC 62304, etc.);
- Mastery of regulations relating to medical devices and/or in vitro diagnostics (MDR 2017/745, IVDR 2017/746, 510k, and/or 21 CFR 820).

You have:

- A Bac +5 (Master, engineering school) in quality assurance and regulatory affairs in the scientific field
- At least 2 years of experience in medical devices and/or in vitro diagnostic medical devices
- A good command of English

We offer you :

- The opportunity to work with an international team with a high technical and scientific level;
- A start-up type work environment;
- Hybrid work (2 days of teleworking/week)
- Offices at the foot of the Eiffel Tower😍
- An attractive package

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