Quality Assurance and Regulatory Affairs Intern

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 clinical decision-making solutions 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, we offer you a 6-month internship to develop your skills and 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 compliance of the QMS with 21 CFR Part 820 and regulation 2017/746;
- Contribute to normative monitoring relating to regulatory requirements (2017/746, FDA, Health Canada, MHRA, Swissmedic, etc.):
- Use the sources made available to identify any new applicable standard and/or applicable standard revision and/or guidance, and become familiar with and master these standards/guidance,
- Analyze these standards / guidance and document this analysis, then establish the action plan necessary for implementation within the framework of the QMS and R&D,
- Monitor and ensure the implementation of the action plan within the company
- Participate in the compliance of the technical files of medical devices with regulation 2017/746 and FDA requirements,
- Participate in the creation of regulatory files for CE certification (Europe), FDA, etc.

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 :

- Prepare a Bac +5 (Master, engineering school) in quality assurance and regulatory affairs applied to medical devices
- Have a good command of English
- Have availability asap

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😍

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