Aesyra SA
EPFL Innovation Park Building C
CH-1015 Lausanne
Switzerland

Contact:
Marco Letizia
Marco.Letizia@aesyra.com
+41762885542

JOB OFFER

Regulatory Affairs and Quality Assurance Senior Specialist

80-100%, starting March/April 2020

Aesyra SA is a MedTech start-up company with head office at EPFL Innovation Park in Lausanne (VD), Switzerland. The mission of Aesyra is to develop, manufacture and commercialize a medical device able to accurately monitor and relieve sleep bruxism using an innovative treatment, a solution for 60 millions of peoples worldwide. In Aesyra's vision, this is the first of a series of innovative products dedicated to common sleep and oral disorders.

We are looking for an experienced person to manage and coordinate regulatory and quality affair activities, ready to join a hard-working team, passionate about taking Aesyra to the next level.

Your skills and competences

- Master or PhD in science, engineering, medicine, pharmacy, or equivalent
- Over 4-year experience in a similar role in the medical device industry (QA / QM / RA / Clinical Affairs)
- Good knowledge of regulatory requirements for medical devices and relevant standards
- In-depth knowledge of European (MDR) and FDA regulatory pathways (510(k), de novo, PMA)
- Experience with ISO 13485 requirements, processes and procedures; good knowledge of QSR
- Experience with ISO 14971
- Experience with ISO 14155 / GCP, good understanding of clinical trial management and post-market surveillance procedures
- Knowledge of Process Validation principles
- Certification as Lead Auditor, to conduct internal and suppliers' audits
- Excellent communication skills and ability to work well with and train others, ability to work efficiently under high-pressure conditions
- Collaborative mind-set, excellent communication capacities, planning, organizing, and self-initiative skills
- Fluency in English (spoken and written)
- Willingness to join a multicultural fast-growing start-up team.

Your responsibilities

- Cover role of PRRC within the team
- Support the management in decision-making concerning QA and RA matters, incl. regulatory strategy
- Implement and manage an ISO 13485-compliant QMS, including aspects of PMS
- Author and maintain Quality Manual, SOPs, policies and records
- Support the team in generating the required documentation and ensuring product compliance, incl. technical documentation
- Lead internal quality audits, lead/support supplier audits
- Manage pre-submission interactions with FDA
- Lead preparation, submission and maintenance of regulatory dossiers in Europe, US, incl. submission to ethical committees, competent authorities and notified bodies
- Manage communications with regulatory bodies
- Supervising clinical trial activities

If interested, please send your application electronically to info@aesyra.com

Marco Letizia, Chief Executive Officer