



**Aesyra SA**  
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## **JOB OFFER**

Regulatory Affairs and Quality Assurance Manager

80-100%, starting from June 2019, to be agreed with the candidate

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.

### Skills and competences

- Master or PhD in science, engineering, medicine, or equivalent
- Over 4-year experience in a similar role in the medical device industry
- Good knowledge of regulatory requirements for medical devices and relevant standards
- In-depth knowledge of European and FDA regulatory pathways
- Experience with ISO 13485 requirements, processes and procedures
- Certification as Lead Auditor, to conduct internal and suppliers' audits
- Excellent communication skills and ability to work well with and train others
- Collaborative mindset
- Fluency in English (spoken and written)
- Willingness to join a multicultural high-growing start-up team.

### Responsibilities

- Support the management in decision-making concerning QA and Regulatory matters
- Implement and manage a ISO 13485 compliant Quality Management System
- Author and revise quality manual, standard operating procedures, policies and records
- Support the team in generating the required documentation and ensuring product compliance
- Lead internal quality audits
- Manage submissions to ethical committees, competent authorities and notified bodies
- Lead preparation, submission and maintenance of regulatory dossiers in Europe, US
- Communicate with National Competent Authorities and other regulatory bodies.

If interested, please send your application electronically at [info@aesyra.com](mailto:info@aesyra.com)

Marco Letizia, Chief Executive Officer