emboflu

JOB DESCRIPTION

QUALITY AND REGULATORY AFFAIRS ENGINEER

Overview

Emboflu is a medical device company, which manufactures an embolic liquid (Class III) for the treatment of Arterio-Venous Malformations. Emboflu is headquartered in Switzerland (Gland) and distributes across the world through a network of dedicated partners.
Emboflu has been created in 2012. It belongs to the group BALT since 2015.
6 persons are permanently on site.
The turnover is growing every year more than 50%. CA 2016: 3.5M CHF.
The company has the CE Mark and is ISO 13485.

Mission of Emboflu:
We are committed in improving the treatment of vascular malformations by bringing new solutions to the Practitioner. We aim to become leaders in innovating technologies, that make a valuable difference in the practice of physicians and ultimately, in patients' lives.

For the growing of the company, we are looking of a QA/RA engineer in order to assist the QA/RA manager

Job Profile

I/ QUALITY ASSURANCE

- Update the Quality Management System, on the basis of the standards and directives in effect and that apply to Medical Devices,
- Assist the QA/RA manager during the internal audits, supplier audits.
- Contribute and Monitor the internal Corrective and Preventive Actions, the complaints, the medical devices vigilance dossiers, and the internal Non-Conformities. Put in place corrective and/or preventive actions with the various players concerned if necessary.
- Contribute to physical and microbiological checks on controlled atmosphere areas and stores,
- Prepares batch documents with a view to the release of manufacturing batches after sterilization. Ensures the release of manufacturing batches after sterilization. Is authorized to block/release all products, components and raw materials.
- Contribute and monitor the test equipment - Maintenance.
- Support the production and technical problems.
- Staff awareness raising and internal training in the company's quality system,
- Contribute to prepare audits and inspections by notified bodies and by relevant authorities,
- Draft protocols and reports for testing.
- Make proposals to Management concerning opportunities for improving and optimizing the quality management system,
- In the absence of the QA/RA manager, is the management's representative with respect to maintaining and continuously improving the quality management system in line with applicable quality standards.

II/ REGULATORY AFFAIRS

- Monitor the relations with notified bodies, the post-market monitoring, and the notification of changes to notified bodies.
- Draft the requisite technical documents for development projects. Formalize the finalized technical dossier. Draft documents required for registrations.
- Participate to the necessary tests, trials and reports.
- Monitor the specific standards of certain countries
- Is an alternate materivigilance

Prerequisites

- Require a Bachelor's degree in Engineering (Masters, PhD). Experience of 2-5 years in Quality and regulatory affairs in medical devices environment. Certified Quality Engineer (CQE) and Medical device experience preferred. Combination of education and experience may be considered (in evaluating experience relative to requirements)
- Working knowledge of current medical devices quality guidelines, basic quality systems regulations and standards (i.e.ISO13485, FDA 21 CFR Part 820 and Directive 93/42/EC)
- Working knowledge of fundamental quality and statistical tools
- Ability to communicate both orally and in written form to multiple levels of the company.
- Attention to detail and organization
- Use of Microsoft Office (Outlook, Excel, Word, PowerPoint)
- Ability to deliver, meet deadlines
- French and English speaking
- Full-time position