NICE, FRANCE

Regulatory Affairs Specialist

MONIA@ELEMED.EU

The company

As a Regulatory Affairs Specialist, you will be responsible for setting up regulatory plans aligned with the business strategy and be the “go-to” person for regulatory affairs activities internally and externally. As well as defining and implementing the European and US regulatory strategy.
You will have the autonomy over your work to make the RA department more robust by developing processes with the support of the Head of RAQA.

You will work with a company investing in people and talent which will give you the opportunity to grow and step up quickly. You will also have the chance to work in an international context and develop your knowledge outside of Europe.

This position will give you the chance to work with a large portfolio of products in different therapeutic areas from Class I to Class IIa.

The responsibilities

- Manage and supervise registration dossiers by coordinating and interacting with internal stakeholders

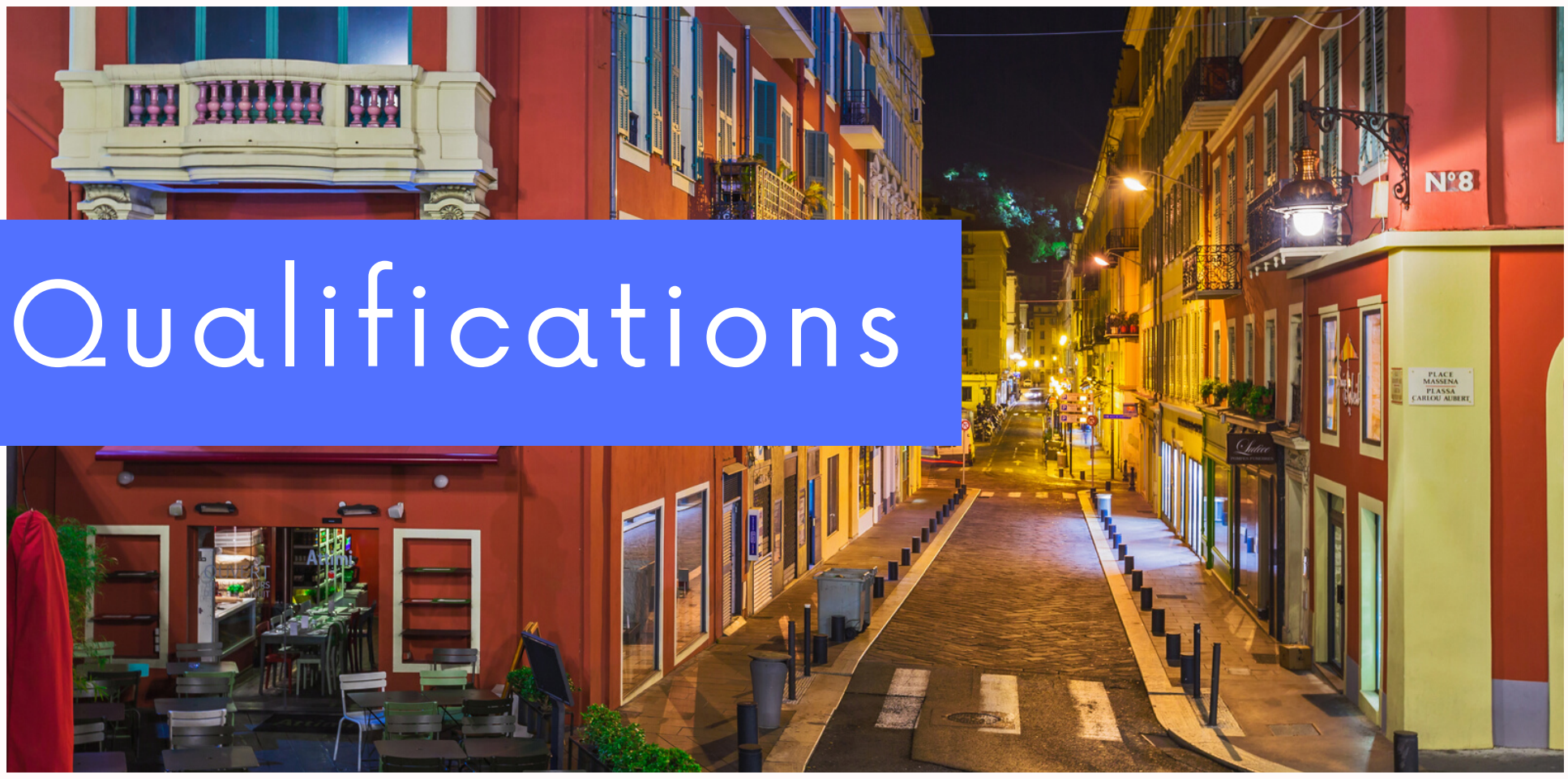
- Build relationships and network with relevant external stakeholders

- Writing, submission for Europe and US

- Write, verify and update technical files for CE marking
- Write, check and keep up to date with the clinical evaluation and investigation files

- Check and validate the instructions, labels, technical sheets, etc. according to the standards and regulations in force

- Write, verify and maintain PMS



Qualifications

- Minimum of 2 years experience in Regulatory Affairs within the Medical Devices industry

- FDA experience/knowledge is a plus

- Fluent in English

INTERESTED IN FURTHER CONVERSATION?

IF YOU ARE INTERESTED IN THIS EXCITING ROLE, PLEASE SEND YOUR APPLICATION DIRECTLY TO:

MONIA@ELEMED.EU