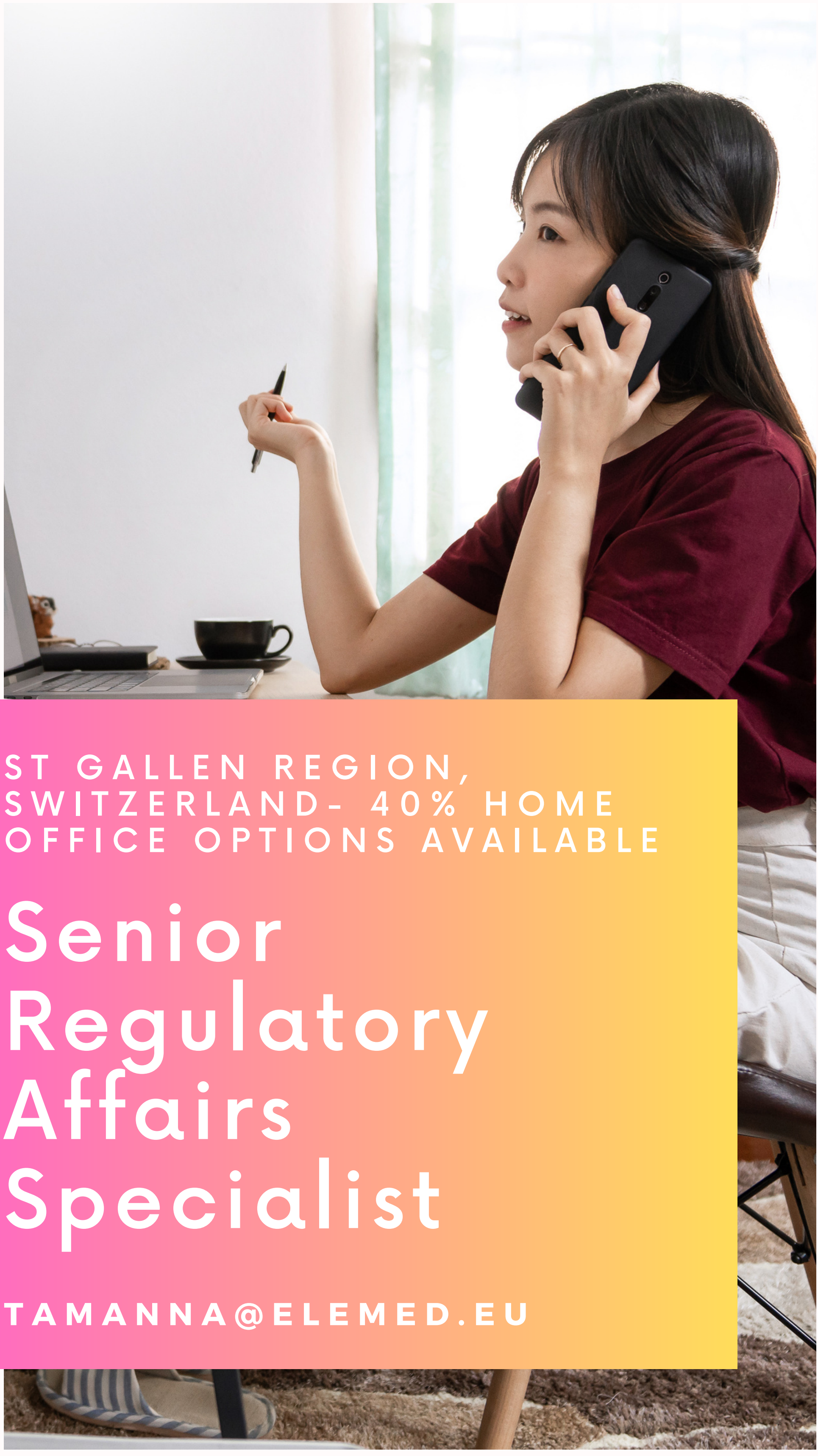


ST GALLEN REGION, SWITZERLAND- 40% HOME OFFICE OPTIONS AVAILABLE

Senior Regulatory Affairs Specialist

TAMANNA@ELEMED.EU

Do you have experience in regulatory affairs for medical devices? Are you looking for an opportunity to take your responsibilities to the next level? Do you enjoy working at the heart of the company, directly on the manufacturing site? If you answered yes to even just one of these questions, take a look at this fantastic opportunity!

The company

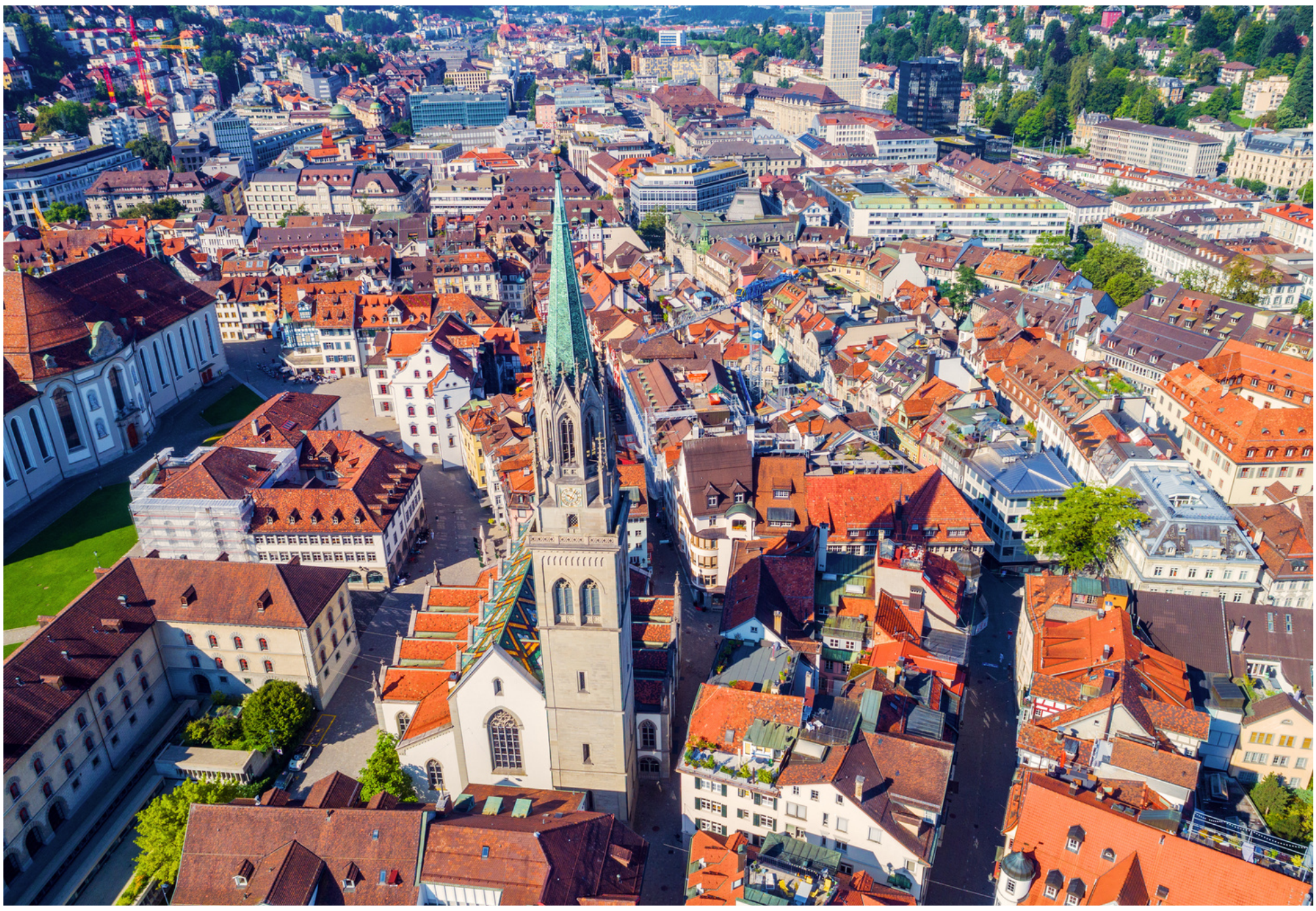
In this role, you will work for a mid-size medical device company, with a strong international presence in Switzerland, Germany, and China. This medical device manufacturer is the market leader in its field, enjoying strong partnerships with some of the world's most renowned MedTech companies, as well as designing and developing its own products.

Owing to a dynamic acquisition strategy, this company has enjoyed fast-paced growth and is entering the next (exciting!) phase of its expansion journey. The regulatory department is strong and committed to excellence with a strong global presence.

The company

In this opportunity, you will be empowered by the Global Head of RA and VP RA/QA to develop your skills over key global projects.

You will be one of the key drivers of the technical documentation process, while also having a great opportunity to work with other departments including QA and production.



The responsibilities

As Senior Regulatory Affairs Specialist, you'll have the following responsibilities

- Manage the lifecycle for the portfolio of products within the European market, while also covering some exciting emerging markets areas
- Develop processes to ensure the compliance of all devices throughout the lifecycle for the EU markets
- Support key relationships with European Authorities, Notified Bodies, and international competent authorities
- Manage notifications of medical devices to the relevant local authorities such as Swissmedic in compliance with the national legislation
- Contribute to the regulatory intelligence and regulatory policy activities within the company
- Be the "go-to" person/subject matter expert for all technical documentation questions
- Perform various activities such as Field Safety Corrective Actions, reviewing and approving promotional materials, verification of labelling and packaging, conducting change evaluations

Requirements

As Senior Regulatory Affairs Specialist, you should have:

- 5+ years of experience in regulatory affairs for the medical device industry
- Experience of hands on the technical documentation file process
- Experience with CE marking would be a bonus
- Fluent in speaking, reading, and writing in English
- Fluency in German would be a bonus

INTERESTED IN FURTHER CONVERSATION?

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

TAMANNA@ELEMED.EU

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