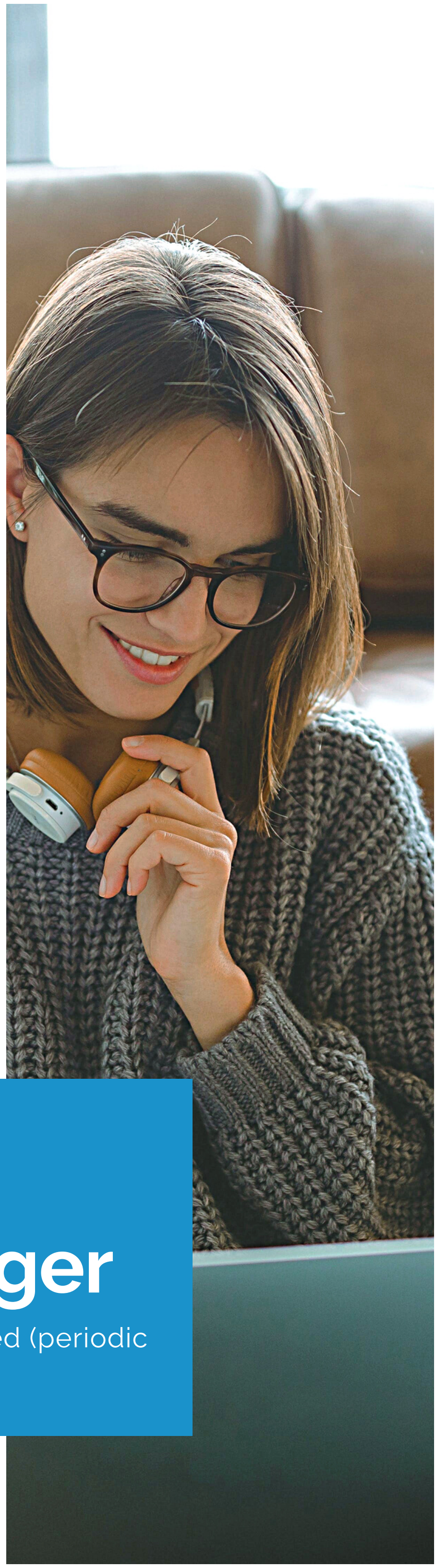

Regulatory Affairs Manager

Zurich, Switzerland or home based (periodic travel to Zurich /Basel required)

elemed | Get in touch with Elena at elena@elemed.eu

Are you a regulatory professional who:

- Loves having a variety of activities in your daily work?
- Enjoys challenging regulatory projects?
- Is passionate about constantly learning new things?
- Has a problem-solving approach to regulatory challenges?

Then we have a really unique opportunity for you!

THE COMPANY

A growing Swiss medical device consultancy is developing a new Regulatory Affairs business unit and is offering a unique opportunity for an experienced regulatory professional to use their skills in a new way. **This is a permanent position**, offering a role blending all the classic regulatory skills in a new context.

THE OPPORTUNITY

This will give you the chance to work on regulatory projects, supporting Swiss companies of all sizes, and help them overcome regulatory challenges. Best of all; **this is <u>not</u> a freelance** position; so you'll enjoy all the normal benefits and security of being permanently employed, with a lot more variety than working for just one manufacturer!

Manager
Regulatory Affairs

THE RESPONSIBILITIES

As regulatory affairs manager, you will cover the A-Z of regulatory activities across a range of different medical devices class I-III.

Regulatory

- Supporting “hands on” regulatory projects for customers on activities spanning the full lifecycle of a medical device: CE marking, new product introductions, regulatory strategy, PMS and more
- Guiding new product development project teams from a regulatory perspective, providing input on design controls
- Creating regulatory strategies for US and EU markets, authoring submissions for those key markets and maintaining contact with the US FDA and/or notified bodies as required
- Supporting with MDR/IVDR strategy and implementation
- Change management: creating regulatory assessment and change notifications for device changes
- Providing solutions and ad hoc consulting subject to the client’s needs

THE QUALIFICATIONS

- 5+ years experience in regulatory affairs, medical devices; working specifically on the product development side of regulatory affairs (i.e CE marking, regulatory strategy, and support to R&D)
- Supporting New product introductions or lifecycle management activities
- Experience OR strong interest in ONE of the following areas: Implants, IVDs, Combination devices, SAMD or active medical devices containing software. (Please specify which on your application)
- Fluent English

Regulatory Affairs Manager

Are you interested?

Please send your application directly to elena@elemed.eu

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