HOME-BASED

(PERIODIC TRAVEL TO ZURICH/BASEL REQUIRED)

Regulatory Affairs Manager In-Vitro Diagnostics

VERONICA@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 company 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 and international IVD companies of all sizes, and helping them overcome regulatory challenges. Best of all; **this is not 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!

The responsibilities

As Regulatory Affairs Manager IVD, you will cover the A-Z of regulatory activities, across a range of different IVD devices Class A - D.

Regulatory

- Supporting “hands-on” regulatory projects for customers on activities spanning the full lifecycle of an IVD 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 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

Qualifications

- 5+ years experience in regulatory affairs, IVD 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
- Fluent English

INTERESTED IN FURTHER CONVERSATION?

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

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