BARCELONA, SPAIN OR
REMOTE POSSIBILITIES IN SPAIN

Principal Regulatory Affairs Manager

VERONICA@ELEMED.EU

Are you a Regulatory Affairs expert who:

- Loves having a variety of daily activities?
- Enjoys regulatory challenges?
- Has a problem-solving approach regarding regulatory matters?

This opportunity is for you!

The company

Do you enjoy working in an environment where Quality, Regulatory, and customers are at the centre of everything you do? Since 1996, the company has been providing its customers with strategic guidance on how to effectively navigate medical device regulations all around the world. Their top priorities are helping their customers to get their products on the market efficiently and effectively, for a wide range of products from AIMD class III to IVDs.

This is a fantastic opportunity to work in a multinational company as a Principal Regulatory Affairs Manager specialised in IVDs based in Barcelona, Spain, and reporting directly to the CEO.

The opportunity

Are you looking for a collaborative environment?

You will have the chance to work with highly innovative products in a challenging environment where you'll develop new skills working on projects independently and using your extensive experience in regulatory affairs.

Best of all, this is a permanent position, so you'll enjoy all the benefits and security of being permanently employed, with a lot more variety than working for just one manufacturer.

Also, the company really values every employee and you will feel part of a team even while working from the comfort of your home.

The responsibilities

- Managing hands-on regulatory projects for customers on different activities across the lifecycle of an IVD device

- Leading new product development projects from a regulatory perspective

- Creating regulatory strategies for US and EU markets, authoring submissions, and maintaining contact with the US FDA and/or Notified Bodies

- Supporting with IVDR strategy and implementation

- Providing solutions and tailored consulting subject to the client’s needs

- Acting as the Authorised Representative in Spain for customers

- Work with multiple clients and deliver an excellent standard of service with high technical know-how

- Provide the CEO with client information and strategy ideas

- Train and develop regulatory professionals on client sites about the new MDR projects

Qualifications

- Minimum 8 years of experience in Regulatory Affairs for IVD devices leading projects independently
- Eligible to work in Spain
- Technical, scientific or engineering background is a bonus

INTERESTED IN FURTHER CONVERSATION?

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

VERONICA@ELEMED.EU