Director Regulatory Affairs – Europe (commercial)

UK, IRELAND, NETHERLANDS, SPAIN or ITALY

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The company

This is an exciting chance to make your mark in a world leading healthcare company, undergoing a pivotal transition. Out of change comes opportunity, and this is a rare opportunity to be part of a company reinventing itself. If you have ever been tied down with overly bureaucratic processes and red tape, and wished for the chance to do it better - now you have it!

Are you an experienced manager looking for a step into a Director role?

Are you interested in working across regulatory affairs activities, as well as keeping your finger on the pulse of regulatory policy through regulatory intelligence?
In this role, you will be THE leader for all COMMERCIAL European regulatory activities for the company, (country registrations).

And, you'll have a seat at the table of the company's Regulatory Council - where you'll be able to bring your ideas and have your voice heard.

This is a multi-country, multi-layered responsibility and a great opportunity for an experienced team manager to take the next step into a more strategic role. The team size is 15 people based all over Europe, covering various responsibilities in regulatory affairs including:

- Local Country registrations across the Europe region for the whole company portfolio across all business units of the company (class I-III)
- Post Market strategy/ FSCA notifications
- Management of communication with the local competent authorities
- Brexit, Swisxit and EU Authorised representative responsibilities

Responsibilities

<u>As Director Regulatory Affairs you will have 4 core areas of responsibility</u>

- Manage all aspects of the European Authorised representative function
- Oversee communication with regulatory agencies and collaborate with the legal manufacturer to respond to open questions/requests
- Submit FSCAs and FCNs to competent authorities and manage questions related to product performance and vigilance activities
- Ensure that timely submissions are made to EUDAMED
- Manage the authorised representative audits that take place post registration
- Ensure SOPs, policies and procedures are updated and in accordance with EU MDR

- Guide the business by providing regulatory expertise for key EU markets
- Your internal partners will be regional and business unit leaders
- Your role will be to foster strong collaborative relationships with these partners in order to achieve business objectives
- Support EU MDR workstreams that impact the EU region (e.g economic operators)
- Support new product development by reviewing regulatory launch strategies and advising on any potential issues for registration in the EU market
- Establish best practices for EU regulatory activities and ensure consistent application across all product line

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Responsibilities

<u>As Director Regulatory Affairs you will have 4 core areas of responsibility</u>

- Keep abreast of changes in regulatory policy, undertake regulatory intelligence, and actively participate in advocacy activities
- Assess the changing social, political and economic regulatory environment for the EU region, and develop regulatory strategies for the maintenance and new product introduction into these markets
- Provide guidance on regulatory changes and opportunities to legal teams and executive management, and advise on EU MDR application
- Represent the company at local and EU trade associations, conferences and events
- Where possible, participate in MDCG working groups

- Lead, develop, and manage the regulatory team
- Formulate the regulatory strategy for the region, managing departmental budgets, and representing the EMEA RA department in corporate company projects
- Recruit develop and retain a team of regulatory professionals across EU
- Ensure the team are trained appropriately and focussed on helping achieve commercial objectives

We are looking for successful regulatory professionals with the ability to manage through change.

If you are excited by the prospect of making a real difference in a broad and cross functional role, get in touch!

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Expectations

- Degree in Life Sciences or Engineering
- 10 years working experience in medical devices
- Strong working experience of regulatory activities in the EU region
- Management experience
- Fluent English
- Strong working knowledge of ISO 13485, MDR, MDD
- Ability to build relationships with other areas of the organisation and strong influencing skills

Interested in this position?

If you are interested in this exciting role, please send your application directly to elena@elemed.eu

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