SENIOR REGULATORY AFFAIRS SPECIALIST

AMSTERDAM (THE NETHERLANDS)
OR CORK (IRELAND)

THE COMPANY

Come and join this leading medtech company. With a brand known globally, innovative devices from Class I-III and a care for quality, they have been recognised as one of the top employers in the industry.

The position represents the division of EMEA, Western Europe and Nordics.

THE ROLE

Assists in the development of regulatory strategy and updates strategy based upon regulatory changes

YOUR RESPONSIBILITIES

- Assesses regulatory intelligence to assist in the development of local, regional, and global regulatory strategies
- Evaluates the regulatory environment and contributes to providing internal advice throughout the product lifecycle
- Identifies requirements and potential obstacles for market access distribution (federal, provincial/territorial state, reimbursement, purchasing groups, etc.)
- Evaluates proposed products for regulatory classification and jurisdiction
- Determines requirements (local, national, international) and options for regulatory submission, approval pathways, and compliance activities
- Compares regulatory outcomes with initial product concepts and recommends changes or refinements based on initial regulatory outcomes
- Negotiates with regulatory authorities throughout the product lifecycle

ESSENTIAL REQUIREMENT

- BS in Engineering, Science, or related degree; or MS in Regulatory Science
- Typically a minimum of 2 years' experience
- Fluent in English

Interested in further conversation?

Please send your CV to monia@elemed.eu to arrange a confidential career discussion.