

Head of Regulatory Affairs Europe/ROW (m/f) *

Reference Number: 1001446

Company Information

Our client is an exciting and innovative specialty pharmaceuticals company with a vision to become a leader in critical care medicine globally through offering solutions in carepathway, education and research to stakeholders, hospitals and systems.

Position

The Head of Regulatory Affairs Europe/ROW, based in the Basel area, is responsible to fulfill regulatory requirements and champion products with European regulatory bodies, resulting in timely and positive regulatory decisions.

Key Responsibilities

- Develop, oversee and execute the European regulatory brand strategy for products
- Understand medical/scientific product data and market needs to develop successful regulatory filings
- Assist in determining resource allocation across brands and liaise with contractors/vendors to support each innovation team/product
- Establish strong relationships with EMA and other relevant agencies through formal and informal relationships
- Lead and develop global dossiers to fulfill requirements of Health Authorities worldwide
- Serve as product advocate and develop beneficial relationships with key regulatory authorities
- Gather feedback to improve product development and regulatory strategy
- Coordinate expert regulatory input to innovation target, product development strategy, core labeling, and marketing strategy
- Support / Contribute to Development of Global Regulatory Function
- Monitor industry trends; anticipate future changes in marketplace and take action to create long-term opportunities and value
- Work with Innovation teams to build global regulatory strategies and execute regulatory submissions and interactions to meet corporate goals.

Candidate Profile

- Must have minimum of 12 years experience in Regulatory Affairs in multiple European countries
- BS, Medical background and advanced degree preferred
- Advanced knowledge of statistics and clinical study design and all aspects of clinical trials
- Experience to early late and marketed product stages of
- Demonstrated strong leadership within the company and externally to Health Authorities who has the ability to influence through a matrix environment
- Matrix management skills with willingness to be heavily involved with day to day work as well as leading global regulatory strategy independently and proactively with very little guidance/supervision
- Demonstrated success within the global regulatory arena across regions (EU, US, China, India)
- Knowledge of drugs and biologics would be an advantage

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If you are interested in this position please email your CV to

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* This job description applies equally to male and female candidates, regardless of the wording used in the text.