ALTER PHARMA GROUP N.V.

TEAM LEADER, REGULATORY SUBMISSIONS

ABOUT OUR COMPANY

Alter Pharma is a Belgian group of pharmaceutical companies with headquarters in Anderlecht (Belgium) and offices in Ireland and the United States. Employing in total over 140 employees, the Group distributes a wide range of pharmaceutical products to pharmacies, wholesalers, hospitals and retirement homes. At the same time, Alter Pharma is a global player on the generics market, with around 15 molecules on the European and US market and a fully stocked pipeline of niche, complex and added value products.

Our values

Our talented staff daily work in accordance with our company values:

- We are proud of our entrepreneurial culture and foster open communication, mutual respect, professionalism and efficient decision-making and we believe that our multicultural organisation is one of our most important competitive advantages.
- We believe that timely and well considered decisions as a response to emerging opportunities and ideas is the key to our success.
- We believe that the success of the company lies in the competence, dedication and motivation of each of our employees.
- We believe that freedom returns flexibility and empowerment returns commitment.

We are currently looking for a talented Team Leader, Regulatory Submissions to help us proactively managing the lifecycle of the medicinal products. The successful candidate must have proven skills in Regulatory Affairs and has at least 8 years relevant experience in RA in the pharmaceutical industry.

You will report directly to the companies' Associate Head of Regulatory Affairs and will be based in our offices in Balbriggan, Ireland.

The job description

The Team Leader, Regulatory Submissions undertakes full responsibility:

- Lead the Regulatory Affairs submission team and coordinate team workload and activities
- Lead preparation of Module 1 documentation, ensure submissions and deficiency questions are properly handled and in timely manner with regards to new applications, renewal and variation procedures
- Maintain required databases, systems and processes in place
- Monitor new legislations and train concerns internal stakeholders
- Work collaboratively with other functions across the organisation
- Liaise with external parties, Health Authorities of EU, customers and contract manufacturers
- Provide support to non-EU clients registration procedures, from due diligence to lifecycle activities
- Proofread and check documents for accuracy and inconsistencies

Your professional profile

- Strong educational background (MSc or higher in life science)
- At least 8 years of pharmaceutical (generics) industry experience including at least 2 years as a manager
- In-depth knowledge of EU regulatory requirements with focus on Module 1 documentation and eCTD submissions
- Good understanding of requirements for new applications, variations and renewal processes in European procedures including MRP/DCP

Your abilities

- Ability to develop and manage high performing teams to achieve desired outcomes
- Strategic thinking, strong problem-solving and analytical skills
- Understanding the scientific principles and regulatory requirements
- Strong communication skills
- Strong sense of planning and prioritization
- Good organisational skills
- Good project management
- Good understanding of and respect for cultural differences and the capacity to work effectively in a multicultural environment
- Fluent English, both written and oral

For more information about our company, please visit www.alterpharmagroup.be. Motivation letter and CV can be sent to recruitment@alterpharma.be.