ALTER PHARMA GROUP NV

GENERICS GLOBAL DEVELOPMENT – RA UNIT
DIRECTOR, REGULATORY AFFAIRS (USA)

ABOUT OUR COMPANY

Milla Pharmaceuticals Inc., subsidiary of Alter Pharma Group NV 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, 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 in our motto: “smarter, better, faster, together” and that the success of the company lies in the competence, dedication and motivation of each of our employees. “Together” we become “faster” in getting to the market, “better” by continuous improving our efficiency and effectiveness and “smarter” by empowering our people.
- We believe that freedom returns flexibility and empowerment returns commitment.

We are currently looking for a talented Regulatory Affairs Director in US to help us proactively managing the lifecycle of the medicinal products. The successful candidate has at least 15 years relevant experience in US Generics pharmaceutical industry.

You will be responsible for providing leadership and oversight of regulatory activities related to pre-submissions and post-approval of US products with FDA.
You will report directly to the companies’ Chief Scientific Officer and will be based in US.

The job description

The Regulatory Affairs Director undertakes full responsibility:

Regulatory Affairs

- Lead and direct an integrated regulatory program related to ANDA and 505(b)(2) products for submission to FDA, including active engagement and formal communication with the Agency
- Detailed content-review of dossiers for submission to FDA. Such a review includes areas related to drug substance, formulation, analytical testing, stability, and manufacturing through packaging. Conformation to regulatory standards suggestive of FDA and ICH guidelines must be adhered too

- You are expected to provide CMC advice on product development through dossier filing, pre- and post-submission communications with FDA, controlled correspondences, pre-ANDA meetings, pre-submissions meeting, citizen petitions, dispute resolutions, responses to deficiencies, post-approval changes, due diligences on product licensing / acquisition, and participation at FDA meetings
- Detailed CMC review of dossiers in accordance with US FDA standards of acceptability and essential completeness of eCTD modules
- Technical review of dossier must allow for Acceptance to File (ATF), avoid any Refuse-to-Receive (RTR) comments from FDA, and confirm robustness assessment of the dossier, thereby leading to a meaningful prediction of FDA approval timelines

Job Specification

- Detailed understanding of generic product development, dossier-filing, and approval.
- Current understanding of regulatory requirements related to Quality by Design, and interpretation of FDA guidances that are applicable to product development phase through commercialization.
- Well-acquainted with not-yet-established or evolving regulatory trends at FDA through seminars and workshops to pre-empt the planning and execution processes on product development programs.
- Areas of technical experience includes CMC knowledge and good understanding of characterization studies required for drug substance, finished product, and container closure systems, along with specifications setting and product performance.
- Essential professional attributes include a detailed-oriented professional with analytical thinking, a team-player attitude, respect and understanding for cultural differences in different countries, efficient utilization of time and resources, and adaptability due to differences in time zones.

The intended role and responsibilities require that the Regulatory Affairs Director will work remotely but be flexible in committing to domestic and international travels to about 15% of total time.

Your professional profile

The successful candidate has a master's degree or higher in Science or related field, with at least 15 years of experience in US Generics pharmaceutical industry.

You have a minimum of 4 years of prior hands-on experience in formulation development or analytical testing of pharmaceutical dosage forms related to oral and injectable dosage forms.
You are an accomplished professional with strong US FDA regulatory background and have at least 12 years of experience in CMC review of scientific details (required for presenting and compiling procedures, data, results, and commentary on pharmaceutical products for ANDA and 505(b)(2) submissions).

Expected to effectively coordinate with Product Development group at global sites (USA, Belgium, Ireland, India), international contract development organizations, and third-party service providers.

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