



Regulatory Affairs Specialist

KEY RESPONSABILITIES:

Regulatory activity for Generics portfolio

- Manages with maximum efficiency the allocated new registrations / renewals / line extensions/ variations, submission and approval processes, according to the global strategy and to the affiliate market needs and Romanian regulations.
- Provides support to the other departments, concerning launching plan, planning of variations, implementation of changes on the market, discontinuation of marketed products.
- Manages the preparation of the specific Romanian packaging items, ensures that the approved texts are promptly sent to the plants and that the final validation is given in accordance with the approvals obtained
- Maintains accurate records of all ongoing/closed regulatory procedures.
- Maintains and develops optimum relationships with regulatory authorities and decision makers.

Promotional activities

- Checks and validates Regulatory compliance of Generics promotional activities with the approved texts within the marketing authorizations, local regulations and company guidelines and standards.
- Provides the regulatory related support documentation needed for price declaration

JOB REQUIREMENTS:

- University Degree in Pharmacy/ Chemistry/ Biology/ Medicine
- Experience in a similar position, 5 years minimum within a multinational company
- Advanced knowledge of MS Word, MS Excel, MS PowerPoint, MS Outlook
- English – Advanced level
- Capability to work as part of a team, respecting the needs and contribution of those involved
- Ability to build relationships across departments and functions and to support a collaborative working environment
- Sense of urgency, punctuality





- Intercultural adaptability and sensitivity
- Good communication skills
- Analytical, strategic thinking, decision making

OTHER DETAILS:

- Location: Bucharest
- Department: Regulatory Affairs, reporting to Regulatory Affairs Manager

Applications/recommendations can be submitted at cariereromania@zentiva.com until January 25, 2021