THE J. MOLNER COMPANY
The Chemistry People

Regulatory Affairs Associate

Job Description

Date Updated: May 20, 2024
Location: Estonia
Department: Regulatory
Reports to: Director Quality Assurance & Regulatory Affairs
Reporting Relationships: N/A
Substitutions: Regulatory Affairs Associate
Job Status: Full Time

Job Summary:

1. Regulatory Affairs Associate is responsible for creating and implementing comprehensive processes for ANDA compilation for the products to be marketed in US.
2. Regulatory Affairs Associate is responsible for creating and implementing comprehensive processes for dossier compilation for the products to be marketed in Canada.
3. Regulatory Affairs Associate prepares the dossiers based on the existing documents and the reports obtained from R/D department, business development department, and quality department, as well as the documents from publicly available sources.
4. Regulatory Affairs Associate works closely with label, insert and carton artwork designer and instructs the designer of the J. Molner and regulatory requirements.
5. Regulatory Affairs Associate reviews the proposed inserts, labeling and artwork, ensures that it is compliant with the relevant regulations.
6. Regulatory Affairs Associate is responsible for post-marketing reporting with FDA and submission of Annual Product Reviews.
7. Regulatory Affairs Associate is responsible for creating and implementing communication system with FDA, and updating it, if needed.
8. Regulatory Affairs Associate works in close contact with Quality Assurance Manager to ensure that all the quality and regulatory related responsibilities are fulfilled.
9. Regulatory Affairs Associate works in close contact with the relevant Research Scientist in J. Molner and Lab Director to discuss the pathway and prepare the dossier in compliance with J. Molner business objectives.
10. Regulatory Affairs Associate attends the inhouse meetings and the conference calls with the contract manufacturing organization, if applicable to the project.
11. Regulatory Affairs Associate attends the conference calls with the consultancy firms that provide regulatory or pharmacovigilance services to J. Molner.
12. Regulatory Affairs Associate prepares and reviews Standard Operating Procedures, when necessary.

13. Regulatory Affairs Associate works in a regulated environment, follows Standard Operating Procedures and all applicable compendial, ICH and regulatory guidelines, API supplier DMF-s (drug master files), US and European Pharmacopeia, ICH and FDA guidelines, scientific literature.
14. Keeps management informed of all key findings and issues.
15. Other duties may be assigned related to job specific agreement between employee and employer.

Qualifications:

• Minimum BSc in Exact Sciences or Life Sciences.

• Experience in regulatory affairs and compliance, pharmacovigilance or closely related activities.

• Capable of working in a regulated environment (well-organized, able to follow strict rules and regulations).

• Strong problem-solving skills. Well-developed interpersonal skills. Ability to get along with diverse personalities.

• Collaborative working style. Professional, ready to cooperate and willing to support team members and company priorities.

• Good written and oral communications in Estonian and English.

• Ability to work on multiple projects and meet timelines.

This job description is not all-inclusive. It acts as a guideline and is subject to change over time. Additional duties may be assigned based on business needs.

I have read and understood the requirements and responsibilities of the position.