Regulatory Affairs Associate

Job ID
394755BR
Juli 02, 2024
Tunesien

Summary

-Contributes and support the development of submission of product registration, progress reports, supplements, amendments, and/or periodic experience reports. Supports all registration activities of the Department to ensure compliance with the requisites of the local pharmaceutical regulatory environment.

About the Role

Major accountabilities:

- Achieve the best product registration with commercially attractive labelling in accordance with registration plan -Maintain and secure product license in terms of CMC/CDS/safety update according to local regulations/law/guidelines, company strategy and global compliance -Ensure compliance with NP4, KRPIA code of conduct, relevant regulations and laws for related CPO activities (DRAGON update, RMP, packing materials, promotional materials/activities, PMS/drug safety reporting etc.) -Foster and maintain good relations with internal and external stakeholders -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Project & stakeholder feedback -Product license update in terms of CMC in agreed timeline -Adherence to Novartis policy and guidelines

Minimum Requirements:
Work Experience:

- Operations Management and Execution.
- Project Management.
- Functional Breadth.
- Cross Cultural Experience.

Skills:

- Analytical Skill.
- Clinical Trials.
- Collaboration.
- Detail Oriented.
- Lifesciences.
- Project Planning.

- Regulatory Compliance.

Languages :

- English.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Division
Development
Business Unit
Innovative Medicines
Standort
Tunesien
Site
Tunis
Company / Legal Entity
TNP0 (FCRS = CH024) Novartis Pharma Services
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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