Regulatory Affairs Associate (FTC)

Job ID
REQ-10050974

5月 02, 2025

South Africa

摘要

-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 Fuse, BeSure, code of conduct, relevant regulations and laws for related CPO activities (DRAGON update, RMP, packing materials, promotional

materials/activities, 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

Minimum Requirements:

Registered with the SAPC. Min BPharm Degree

Work Experience:

- Regulatory experience min 3-5 years. Able to create and submit eCTDs.
- Functional Breadth.
- Cross Cultural Experience.
- Operations Management and Execution.
- Project Management.

Skills:

- Analytical Skill.
- Collaboration.
- Detail Oriented.
- Lifesciences.
- Project Planning.
- Regulatory Compliance.

Languages:

- English.

Why Novartis:
Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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

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Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Innovative Medicines

地点
South Africa

站点
Midrand

Company / Legal Entity
ZA01 (FCRS = ZA001) Novartis SA (Pty) Ltd.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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