Regulatory Affairs | People with Disability Learnership

Job ID
REQ-10039252
fév 04, 2025
Afrique du Sud

Résumé

To provide support to the RA department to ensure timely submissions and approvals of amendments in line with the submission plan and to meet regulatory objectives.

About the Role

Major accountabilities:

- Understanding the Medicine Act and Pharmacy Act and the related Regulations and guidelines and how these influence the Regulatory Environment.
- Understanding the elements of the Marketing Code.
- Preparation and submissions of regulatory applications to SAHPRA.
- Proof reading of artwork components.
- Supporting compliance activities within the RA team
- Being an active member of the RA team, participating in all team activities, meetings and gathering
- Support the RA team to meet its overall objectives.

Key performance indicators:

- Efficient support has been provided to the RA department for compliance activities.
- All applications are submitted in line with the submission plan and meets all the requirements as specified by SAHPRA.
- Adherence to cGMP and SOPs.
- Training conducted according to program.
- Compliance with the relevant Act, Regulations, and guidelines.
- Compliance with all aspects of the Code of Conduct and Novartis Policies and Procedures.
- Living the Novartis values and behaviours.

Minimum Requirements:

- Minimum: Matric (grade 12), BPharm or Science degree. Honours or Master's degree with exposure to Regulatory Sciences or experience in Regulatory Affairs will be an advantage.

Skills:

- Strong interpersonal and communication skills.
- Highly organized.

- Self-starter
- Ability to manage multiple projects and consistently meet deadlines.

Languages :

- English.

The Company's approved Employment Equity Plan and Targets will be considered as part of the recruitment process. As an Equal Opportunities employer, we actively encourage and welcome people with various disabilities to apply. Novartis recognises, appreciates and values diversity & inclusion.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

Division
Development
Business Unit
Innovative Medicines
Emplacement
Afrique du Sud
Site
Midrand
Company / Legal Entity
ZA01 (FCRS = DEL) South Africa
Functional Area
Autres
Job Type
Full time
Employment Type
Early Career (Fixed Term)
Shift Work
No
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