

Regulatory Affairs Portfolio Manager

Job ID

REQ-10089433

Oct 06, 2026

LOC_ZA

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 DBE/MCA, relevant local regulations and laws for related CPO activities (RIM updates, RMP, product packaging material, promotional materials/activities, g 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.

Key performance indicators:

- Manage assigned product portfolios across multiple therapeutic areas.
- Develop and execute regulatory plans for new registrations, variations, renewals, safety updates, and dossier maintenance activities.
- Support accelerated approvals, line extensions, new indications, and product launches.
- Maintain current product licenses and ensure alignment with global regulatory strategy.

Minimum Requirements:

Work Experience:

- Manage complex product portfolios and regulatory work plans.
- Prioritize submissions, coordinate resources, and track milestones.
- Lead follow-up activities for approvals, health authority feedback, and implementation actions.
- Support business continuity through handovers, portfolio planning, and workload management.
- Partner with Medical, Quality, Supply Chain, Pharmacovigilance, Commercial, Global Regulatory Affairs, manufacturing sites, and external service providers (Cross Cultural Experience).
- Build and maintain effective relationships with health authorities and industry stakeholders.
- Provide regulatory guidance and influence cross-functional decision making.

Skills:

- Strong regulatory knowledge of South African pharmaceutical legislation and SAHPRA processes.
- Effective project management and prioritization skills.
- Attention to detail and dossier quality.
- Strong stakeholder management and communication capabilities.
- Ability to manage multiple submissions and products simultaneously.
- Regulatory systems knowledge (e.g., Regulatory Information Management systems, eCTD processes, regulatory

databases).

- Cross-functional collaboration and compliance mindset.

Languages:

- English.

Education & Qualification

- B.Pharm. Registration with SAPC.
- Regulatory Experience: 3-5 years.

Role Requirements

Division

DIV_GD

Business Unit

Development

Location

LOC_ZA

Site

Midrand

Company / Legal Entity

ZA01 (FCRS = ZA001) Novartis SA (Pty) Ltd.

Functional Area

FCT_RD

Job Type

Full time

Employment Type

Regular

Shift Work

No

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