

Regulatory Affairs Portfolio Manager

Job ID
REQ-10089433
Окт. 06, 2026
Южноафриканская Республика

Сводка

The Regulatory Affairs Portfolio Manager is responsible for managing a portfolio of pharmaceutical products throughout their regulatory lifecycle, enabling timely patient access, maintenance of marketing authorizations, and compliance with local regulatory requirements and Novartis standards. The role leads the planning, preparation, submission, implementation, and tracking of regulatory activities, while serving as the strategic regulatory partner to internal and external stakeholders.

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.

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Дивизион
Development
Business Unit
Development
Место
Южноафриканская Республика
Сайт
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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