Regulatory Affairs Pharmacist (Fixed-Term)

Job ID
REQ-10058687

8月 01, 2025

South Africa

摘要

- To support registration/approval of new products, line extensions, new indications, clinical trials, variations, support regulatory maintenance activities of the registered base portfolio, ensure optimization and regulatory compliance. Support regulatory maintenance activities and ensure optimization and compliance for registered as well as managing all regulatory matters in all spheres of activity [Registration, Production/NTO, Marketing supply chain (SC), Patient safety (PS), Quality Assurance (QA), etc.] and to provide internal and external scientific and marketing advice/expertise. To support submission and communication of PV related reports, QA related matters.
- Support in engagement and collaboration with internal stakeholders as well as establishment and maintenance of strong working relationships with key external stakeholders.
- To support in monitoring and communication of regulatory requirements, intelligence, and policy to facilitate strategic planning for product registration, maintenance of registered base portfolio, clinical trials, policy shaping, capability building and harmonization initiatives across Southern Africa countries (SAC).

About the Role

Major accountabilities:

- Successful implementation of regulatory strategies and planning & execution of registration plans/projects related to submissions and approvals for new products, line extensions, new indications, renewals, clinical trials, safety label changes and quality/CMC variations.
- Performance of due diligence of dossier information/registration documents received from global and other appropriate sources. Ensure timeous compilation, submission, and approval of variation applications. Review and submission of all variations/amendments according to the Global and HA Guidelines.
- Support in engagement & collaboration with internal stakeholders as well as establishment and maintenance of strong working relationships with key external stakeholders.
- Support development and maintenance of dashboards and trackers designed to improve regulatory processes within SAC.
- Monitor, identify and communicate emerging policy information and regulatory intelligence. Support collection and maintenance of regulatory requirements, monitor internal and external solution trends (CTA Hub, third party etc.)
- Support and update local/Regional Working Practices or SOPs when required.
- Ensure adherence to Global and local/regional processes.
- Evaluation of changes for impact on product supply. Ensure the relevant stakeholders e.g., Supply Chain Management, QA and Marketing are aware of any impact.
- Maintain all necessary Novartis databases (e.g., DRAGON, REDI-GO, etc.) to always ensure regulatory compliance.
- Responding to the requests adequately, satisfactorily, and timeously for both internal and external customers.
- Provide technical and scientific support to Medical, Market Access, Supply Chain, Marketing and QA. Review and approval of marketing promotional materials
- Ensure prompt submission of post approval commitments, PSUR submissions, RMP submissions, SLC updates and ensure timely responses to HA as required.
- Ensure issues of non-compliance are handled with urgency and appropriate channels are engaged in a timely manner when necessary.
- Ensure compliance to global and local KPIs.
- Drive collaboration within RA team and cross functionally.
- *Corporate Governance:* Performing all daily activities in line with the Novartis policies and Code of Conduct
- Support Novartis culture journey and role model Novartis V&B.

Key performance indicators:

- Number of achieved standard and stretched submissions and registration/approval milestones/deliverables related to new registration, line extensions, new indications, variations, renewals, annual retentions, clinical trials.
- Ensure timely submission and communication of PV related reports (e.g. PSUR, RMP, HA request, safety concerns, etc.) and QA related matters.
- Achievement of Regulatory compliance deliverables as per global/regional/cluster targets within the assigned county/cluster.
- Proactive communication of new and evolving regulatory requirements to relevant stakeholders.

- Timely and accurate tracking of relevant information.
- Strong working relationships with key stakeholders (HAs and other external stakeholders)
- Maintaining minimum of 95% DRAGON compliance in update of new received post distribution changes to normal country folders and brand safety folders
- Keeping and improving strong relations with Health Authority's officials
- Product Deliveries to the markets according to plans (no stock outs due to out of compliance).
- Providing regulatory guidance on promotional material and support with HA approvals.
- Provide technical and scientific support to Medical, Market Access, Supply Chain, Marketing and QA.

Minimum Requirements:

B.Pharm

Computer literate MS office, excel and PowerPoint

Work Experience:

- Minimum 2-4 years ' experience in pharmaceutical regulatory affairs environment.
- *Knowledge and experience: Knowledge of Regulatory requirements for Medicines in the Southern Africa countries e.g. Botswana, Namibia, Zambia, Zimbabwe, Mauritius, etc.*
- A good understanding of pharmacology, pharmaceutical and clinical data and the pharmaceutical market
- Ability to implement and drive execution.
- Behaviours: Attention to details, Pro-active, People-orientated, Organizational awareness.
- Project management
- Ability to travel and represent the organization
- Demonstrated experience to collaborative effectively with other functions

Skills:

- Analytical and Interpretive;
- Detail oriented and organized;
- Ability to set standards and objectives and monitor progress;
- Prioritize workload to tight deadlines;
- Excellent communication;
- Cross functional ability/Good interpersonal skills;
- Innovative, problem solving and decision-making ability

Languages :

- Fluency in English as a business language. Portuguese/ French is a plus.

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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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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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