Regulatory Affairs Specialist | 12 Month Fixed Term Contract

Job ID
REQ-10066815

11月 21, 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 activities:

- 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 escalate emerging policy information and regulatory intelligence. Support collection and maintenance of regulatory requirements, monitor internal and external solution trends (CTA Hub, third party etc.)
- Communicate new and emerging regulatory requirements to RA colleagues and relevant line functions via written communication such as newsletters, information e-mails.
- 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.
- Maintenance of relevant regulatory databases.
- Maintain all necessary Novartis databases (e.g., DRAGON, NRV, etc.) to always ensure regulatory compliance.
- Responding to the requests adequately, satisfactorily, and timeously for both internal and external customers.
- Timely, accurate and proactive regulatory related communication of general or project specific items to key stakeholders as appropriate.
- 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:

Education (minimum/desirable):

- B.Pharm or life sciences degree or equivalent
- Computer literate MS office, excel and PowerPoint

Work Experience/ Professional requirement:

- 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, Angola, Madagascar, Malawi & Mozambique.
- A good understanding of pharmacology, pharmaceutical and clinical data and the pharmaceutical market.
- Ability to implement and drive execution

Skills:

- Analytical and Interpretive
- Detail oriented and organized
- Ability to set standards and objectives and monitor progress
- Detail Oriented.

- Prioritize workload to tight deadlines
- Excellent communication
- Cross functional ability/Good interpersonal skills
- Innovative
- problem solving and decision-making ability
- Project Planning
- Regulatory Compliance

Languages :

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

Novartis South Africa is committed to promoting equity (race, gender, and disability) through the filling of this post with a candidate whose transfer/promotion/appointment will promote representivity in line with the numerical targets as contained in our Employment Equity plan. While we are prioritizing designated groups, our selection process will still be based on the most suitable candidate, with the necessary skills and experience, as outlined in the job description.

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部门
Development

Business Unit

Development

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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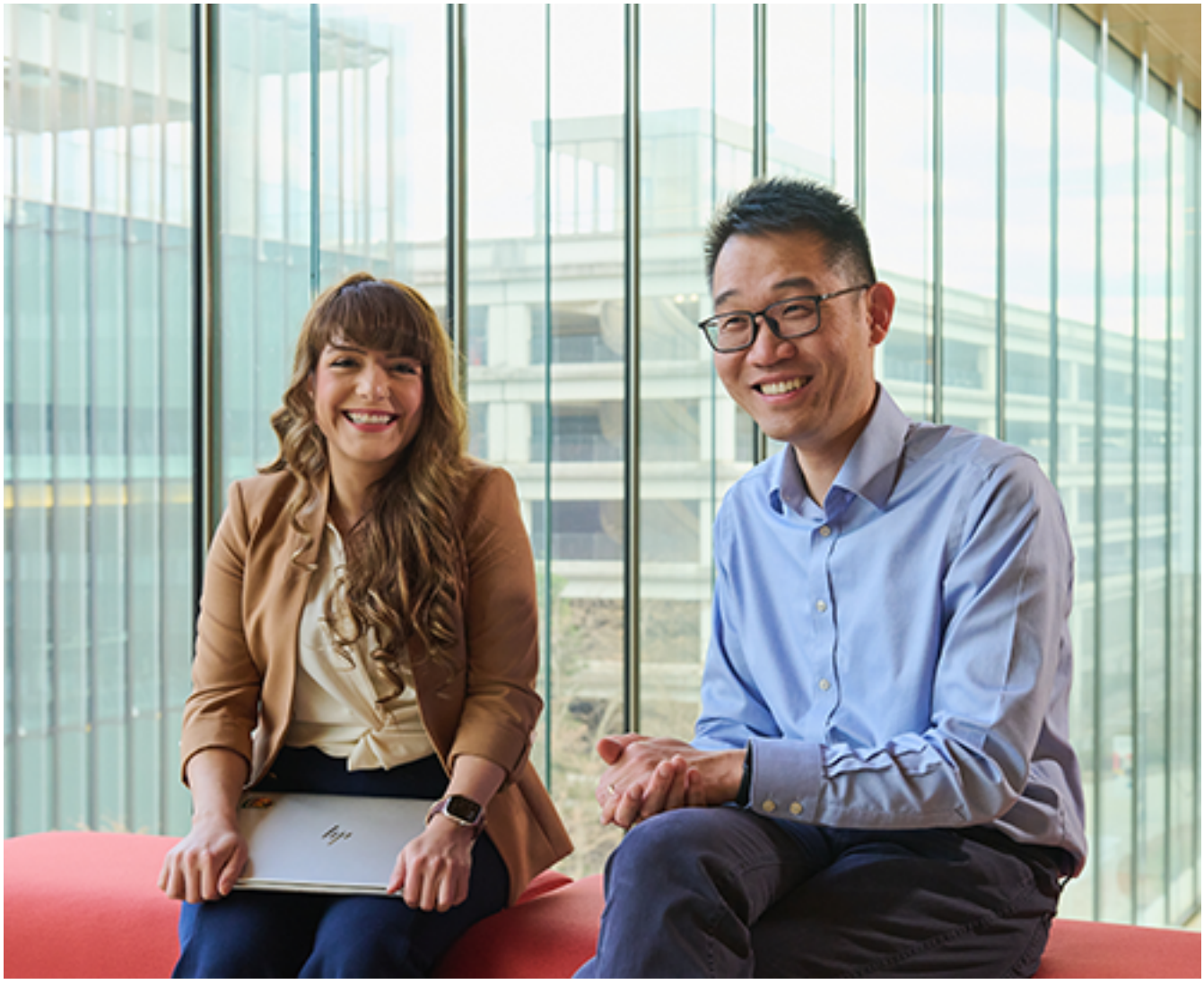

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