Reg Affairs Manager

Job ID
REQ-10049473

4月 17, 2025

Ivory Coast

摘要

The registration of new drug products and the maintenance of registration of approved drug products to ensure viability of these products in the marketplace for the assigned portfolio. To be key Health Authority interface with Novartis on development, in-review and marketed products in the assigned portfolio. To ensure compliance stand-ards and deliverables are always met for the allocated portfolio.

About the Role

Major accountabilities:

- New Product Registrations/Line Extensions With minimum supervision, organise and take a key role in Health Authority interactions, evaluate, perform risk assessment and mitigation where necessary (under supervision of the RA Cluster Head), prepare and submit drug registration applications in a timely manner and follow through the application during the

evaluation phase to achieve a successful outcome.
- Works with TMO and CTA Hub to ensure submission and maintenance of clinical trials in FWCA countries
- Regulatory compliance - Implements accurately and timely measures aiming at the maintenance and regulatory compliance of the Novartis assigned registered product range. Is accountable for assigned portfolio to comply with relevant Novartis standards (DRAGON, CCEx, REDI-GO, REDI RR, COSTA™) and policies as well as all relevant legal and regulatory requirements. In addition, undergoes suitably qualifications and assigned training to fulfil internal and external compliance standards
- Works with QA in the management of complaints of the assigned portfolio
- Provide support as needed to RA Head such as preparation and coordination of presentations and relevant regional overviews for portfolio.
- License maintenance activities: ensure timely availability of key elements to support successful licenses in the markets and optimal tracking. Eg renewals, CMC variations, PTs, etc...
- Manage and Track regulatory databases (e.g. Health Authority submissions and approvals in FWCA countries, CDS (triggered by safety issues), RMP updates and PSUR) and prepare metric reporting according to AGL processes and KPIs
- Provide operational support for obtaining up-to-date Regulatory Intelligence and other regulatory support Information
- Act as DRAGON Super user for CPO RA as needed.
- Ensure RMP, PSUR, CDS updates submission and HA approvals and adequate tracking and communication to HQs as needed.
- Ensures quality and compliance of regulatory activities in FWCA by adhering to corporate processes, business guidance, SOPs.
- Responsible for implementing RA SOPs, specific process/quality standards in FWCA.
- Addresses audit findings, and partners with RA CPO Head, CPO QA to improve efficiency and functionality, and maintain CPO compliance.
- Oversight of out-of-compliance cases in FWCA region, tracking of cases, identification of root causes and solutions, rapid implementation, and regular report to Management.
- Review of Promotional Material - Review promotional material for assigned products. Liaise with Marketing and Communications personnel in disseminating appropriate information on the Novartis product range.
- Relationships within and outside the company - Develop and maintain good working relationships with other Novartis departments both locally and with Head Office and with health authority and industry bodies. Provide regulatory advice as necessary.
- Represent Regulatory Affairs on local brand teams as required. Ensure all business activities comply with relevant Acts, legal demands and ethical standards.
- Acts as deputy to the RA Head when needed.

Key performance indicators:

- Achieved standard and stretched regulatory milestones and deliverables

- Timely submissions and approvals with the best possible, competitive label based on available data.

- Where applicable, successful participation in HA interactions to achieve business objective.

- Provides comprehensive regulatory feedback to achieve global business objectives.

- Achievement of regulatory compliance targets as set for RA globally and CPO regulations

Minimum Requirements:
Work Experience & Skills:

Minimum 3 years experience in regulatory affairs.

Dealing with a wide variety of registration projects and issues. Tracked successful interactions with Health Authorities is advantageous.

Strong self-organising and analytical skills

Good understanding of business models in assigned countries

Good communication and negotiation skills

Team oriented

Shows cultural awareness

Languages :

- Fluent in French & English (oral and writing)

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部门

Development

Business Unit
Innovative Medicines

地点
Ivory Coast

站点
Ivory Coast

Company / Legal Entity
CI02 (FCRS = CI002) NPHS AG Ivory Coast NTLE

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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