Regulatory Affairs Manager

Job ID
REQ-10036644

1月 13, 2025

Saudi Arabia

摘要

The RA Manager will be responsible to develop & execute submission & approval strategy for all regulatory activities & to ensure ethical conduct and compliance with applicable national and international laws, codes and regulations.

About the Role

- Manage, supervise and coach DRA associates to achieve the business objectives in term of new Launches and life cycle maintenance activities.
- Provide adequate training and guidance to all junior regulatory associates as relevant
- New Product Registrations - With no supervision, set up the strategy evaluate, prepare and submit drug registration applications in a timely manner and follow through the application during the evaluation phase to achieve a favorable outcome
- Maintenance of registered products - With no supervision, maintain registration of currently approved products

- Product Information and Consumer Information - With no su pervision, maintain product information and consumer information ensuring the correct use of the approved versions of these documents
- 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, such as the SFDA.
- Provide valuable regulatory advice as necessary.
- Assist Medical Information and Quality Assurance with product detail requests wherever feasible.
- Ensure the compliance of Regulatory database system ' s content & data maintenance activities (Dragon, Regulatory Intelligence Database ...etc.).
- Create, maintain, Review & approve products artworks & leaflets & set-up the proper plan for implementation.
- Create, review & maintain BSS for all promoted products.
- Review and approve Printed Packaging Material Sheet (PPMS) received via AQWA.
- Monitor, Communicate & distribute All SFDA new regulations & guidelines among all the concerned departments in the CPO, Regional RA team and Global RA team.
- Review, Analyze and implement All SFDA new regulations & guidelines.
- Review & approve promotional materials & activities in compliance with applicable company & country regulations & policies.

Key Performance Indicators

- The timely registration of new drug products.
- Accurate & timely maintenance of products life cycle management.
- Accurate & timely update for Novartis products labels, leaflets and safety information.
- Timely & accurate development & implementation of new artworks for leaflets & folding boxes.
- High regulatory compliance percentage for SALTO reports & DRAGON & all other relevant databases.
- Keep the relation with all related parties (inside & outside NVS) at the top level of respect, confidence & reliability.
- Performance management and coaching of the relevant DRA team.
- High regulatory compliance percentage for SALTO reports & DRAGON.
- Compliance of the promotional materials with the registered/approved PI.

Ideal Background

Education :

- Bachelor Degree in pharmacy or any equivalent degree.
- Master degree is preferred.

Experience:

- 5-7 Years in Regulatory Field.
- Deep understanding of SFDA and GCC regulatory system and rules.
- Strong Management skills.
- Excellent organization skills and ability to work on a number of projects with tight timelines is required.
- Strong Negotiation & Analytical skills
- Strong Interpersonal & Communication skills
- Excellent Computer skills (Word, Excel & PowerPoint).
- Fluent in Spoken & Written English.

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部门
Development

Business Unit
Innovative Medicines

地点
Saudi Arabia

站点

Riyadh

Company / Legal Entity
SAP0 (FCRS = CH024) Novartis Consulting AG

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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