HEAD OF REGULATORY AFFAIRS – Consumer Health

Application Period
19 Feb. 2019 – 05 March 2019

Reference Code
HORACH2019

Division
Consumer Health

Company
Bayer (Pty) Ltd

Department
Regulatory Affairs

Location
Isando

Functional Area
Regulatory Affairs

Position Grade
VS 1.3

Employment Type
Permanent

Work Time
Regular

YOUR TASKS AND RESPONSIBILITIES

Responsibility for the leadership of the CH regulatory team for South Africa. Responsible for all regulatory affairs activities of CH including all maintenance and development product activities dealing with the relevant Health Authorities in relation to pharmaceuticals (Non-Rx) , medical devices, cosmetics, CAMS and food supplements marketing authorization /permission / notification. Contribution to the business growth in the sub-cluster providing guidance and advice to local business and regional/global functions on the regulatory strategy development and processes as well as issues and risks.

- The position incumbent decides on local regulatory strategic and operational matters to fulfil the local business strategies, in coordination with the local functions and with close coordination with Country Regulatory Affairs Head, Regional Head and other Global regulatory units.
- Ensures transparent, timely and efficient communication with business supply chain and other local functions to achieve common decisions.
- Managerial responsibility of the CH regulatory affairs staff, including talent management and people development.
- Where locally relevant, or incollaboration with the Country Head and the (sub-) regional RA head; responsible for the preparation of local budgets and the dequate hiring and training of staff.
- Identifies resource requirements and allocates resources to meet regulatory needs.
- Ensures early identification of conflicts between projects and ensures transparent and aligned prioritization.
- Ensures the preparation of the application files (Dossiers) for products based on the documentation provided from GRA Regulatory

- Ensures the preparation of the application files for clinical trials based on the documentation provided from GRA Partners in accordance with the local regulations and presents them to the respective authorities, where locally relevant.
- Supports the Country Quality Head and/or the Responsible Pharmacist to plan, manage GMP and/or Applicant inspection requirements incl. GMP applications, inspections and certifications of Contract Manufacturing Sites as locally relevant.
- Regulatory Quality Management: Responsible for local and internal compliance to regulatory affairs relevant processes and systems.
- Ensure regulatory compliance for a sustainable life-cycle management.
- Labelling and CMC changes are performed in accordance with local regulations and relevant Bayer SOPs (Priority Levels).
- Responsible to represent Bayer as a competent reliable partner to the local Health Authorities in all regulatory matters, to enable timely approvals with optimal labels (pi's)
- Proactively shapes the regulatory environment in the country. Ensures appropriate representation of Bayer in the local industry associations.
- Builds strong regulatory networking with national regulators, local industry organizations and key opinion leaders.
- Provides local RA intelligence: Identifies current and emerging national regulations which impact the drug development and/or marketing processes and ensures appropriate contribution and communication with all involved areas. Contributes actively to design and assessment of RA strategic options as a member of regional regulatory teams.

WHO YOU ARE

Experience & Qualifications

- B.Pharm Degree, with a post-graduate degree in Pharmacy, Life Sciences or equivalent scientific degree an added advantage.

- Minimum of 5 years pharmaceutical industry experience in regulatory affairs, with at least 3 years of proven experience in health authority interactions, in managing projects and resources.

Skills

- Ability to communicate effectively bth orally and in writing, with proven persuasive, assertive and negotiating skills.

- Convincing presentation skills required,

- Demonstrated cross-function abilities

- Communication skills

- Strong managerial and leadership skills to lead and motivate cross functional teams and direct reports, in line with our company LIFE Values.

- Strong team building abilities.

- Solid and proven knowledge of all compliance aspects related to the regulatory affairs function.

- Thorough knowledge of company policies and procedures. Detailed understanding of the operation procedures and policies of the national or agency or deep experience with a related national health authority.
- Ability to develop effective solutions to diverse and complex business problems.
- Ability to clearly voice Bayer's and Global Regulatory Affairs needs with a high degree of accuracy and reliability.

CONTACT US

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