



**PASSION TO INNOVATE** | **POWER TO CHANGE**

# CONSUMER HEALTH – REGULATORY AFFAIRS ASSOCIATE – ISANDO

**Application Period**

12 January 2021 – 25 January 2021

**Reference Code**

CH/RA/GAUTENG/Isando

**Division**

Consumer Health

**Company**

Bayer (Pty) Ltd

**Department**

CH Regulatory Affairs

**Location**

Gauteng

**Functional Area**

CH Regulatory Affairs

**Position Grade**

VS 1.1

**Employment Type**

Permanent

**YOUR TASKS AND RESPONSIBILITIES**

1. Compile applications (in paper, NeeS or eCTD formats) in line with the latest relevant laws and regulations and submit within specified timelines in order to support the business and RA strategic objectives.
2. Receive, prepare and submit all applicable variation applications including SmPC and leaflet, resolutions and respond to any other correspondence received from health authorities.
3. Support all new product launches/re-launches, which includes: Conducting dossier gap analysis to identify changes, review and approval of artwork, promotional and advertising materials, variation preparations and submissions.
4. Review and approval of product artwork, promotional and advertising materials in accordance with current Health Authority regulations and standards.
5. Support QA with Annual Product Quality Review
6. Align and collaborate with internal stakeholders and third-party manufactures to ensure compliant, good quality dossiers are received to submit it to the Health Authorities
7. Establish new, build and maintain relationships with internal and external stakeholders, including health authorities, 3rd party manufacturers, industry bodies and consultants.



## WHO YOU ARE

### Experience & Qualifications

- Minimum of 2- 3 years in medicine Regulatory Affairs, Medicine Registration and Quality Control prior to appointment. Consumer Health regulatory affairs experience is an advantage
- Must have National Diploma in analytical Chemistry or equivalent
- B. Tech.: Pharmaceutical Sciences or equivalent

### Skills & Knowledge

- Good analytical, organizing and communication skills,
- Excellent interpersonal skills and team player.
- Good Computer literacy

### CONTACT US

Address  
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