

## Regulatory Affairs Specialist

Job ID  
REQ-10058966

7月 30, 2025

Saudi Arabia

### 摘要

Be the bridge between innovation and patient safety—As a Regulatory Affairs Specialist in Saudi Arabia's dynamic healthcare landscape, you'll play a pivotal role in shaping the future of medicine. From ensuring compliance with SFDA regulations to accelerating access to life-saving therapies, your expertise drives both public health and industry growth. Join a mission where precision meets purpose, and every regulation you navigate brings better care to millions.

### About the Role

#### Major Accountabilities

- New Product Registrations - With supervision, evaluate, and prepare 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 supervision, maintain registration of currently

approved products (initiation and preparation of variation/ and renewal applications as per the plan communicated from the DRA manager/Head).

- Coordinate with DRA manager/head to ensure correct and speedy implementation / consignments as per the approved applications (variation/ renewal/ site transfer/ site registration/leaflet update).
- Maintain, with supervision, the internal DRA database accurate and updated: Dragon/DASA
- Relationships within and outside the company - Develop and maintain good working relationships with other Novartis departments both locally and with Head Office and with third-party vendors.
- With Supervision, Review PPMS and ensure AQWA Launch request are prepared and launched on time.
- With Supervision, ensure full support to Global regulatory compliance initiatives in Saudi.

#### Minimum Requirements

- Pharmacy or related science degree.
- Minimum 1 year of RA Experience in reputable pharmaceutical company.
- Experience handling a portfolio/product and dealing with stakeholder such as SFDA and governmental agency.
- Must be Saudi national.

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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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