

# Regulatory Affairs Associate

Job ID  
394755BR  
Jul 02, 2024  
Tunisia

## Summary

-Contributes and support the development of submission of product registration, progress reports, supplements, amendments, and/or periodic experience reports. Supports all registration activities of the Department to ensure compliance with the requisites of the local pharmaceutical regulatory environment.

## About the Role

### Major accountabilities:

- Achieve the best product registration with commercially attractive labelling in accordance with registration plan -Maintain and secure product license in terms of CMC/CDS/safety update according to local regulations/law/guidelines, company strategy and global compliance -Ensure compliance with NP4, KRPIA code of conduct, relevant regulations and laws for related CPO activities (DRAGON update, RMP, packing materials, promotional materials/activities, PMS/drug safety reporting etc.) -Foster and maintain good relations with internal and external stakeholders -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

### Key performance indicators:

- Project & stakeholder feedback -Product license update in terms of CMC in agreed timeline -Adherence to Novartis policy and guidelines

### Minimum Requirements:

#### Work Experience:

- Operations Management and Execution.
- Project Management.
- Functional Breadth.
- Cross Cultural Experience.

#### Skills:

- Analytical Skill.
- Clinical Trials.
- Collaboration.
- Detail Oriented.
- Lifesciences.
- Project Planning.

- Regulatory Compliance.

#### Languages :

- English.

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Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?

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Division

Development

Business Unit

Innovative Medicines

Location

Tunisia

Site

Tunis

Company / Legal Entity

TNP0 (FCRS = CH024) Novartis Pharma Services

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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