# Regulatory Affairs Specialist

Job ID
REQ-10023226

9月 20, 2024

Serbia/Monten.

## 摘要

-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:**

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

**Skills:**

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

**Languages :**

- English.

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部门
Development

Business Unit
Innovative Medicines

地点
Serbia/Monten.

站点
Serbia

Company / Legal Entity
RSP0 (FCRS = CH024) NPHS RO Serbia

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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