

# Regulatory Affairs Specialist

Job ID  
REQ-10023226  
Sep 20, 2024  
Serbia

## Resumen

-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.

**Why Novartis:** Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other.

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

<https://www.novartis.com/about/strategy/people-and-culture>

**Join our Novartis Network:** Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

División

Development

Business Unit

Innovative Medicines

Ubicación

Serbia

Sitio

Serbia

Company / Legal Entity

RSP0 (FCRS = CH024) NPHS RO Serbia

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

[Apply to Job](#)

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } }

Job ID

REQ-10023226

## **Regulatory Affairs Specialist**

[Apply to Job](#)

---

**Source URL:** <https://prod1.adacap.com/careers/career-search/job/details/req-10023226-regulatory-affairs->

*specialist*

**List of links present in page**

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. <https://www.novartis.com/careers/benefits-rewards>
4. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Serbia/Regulatory-Affairs-Specialist\\_REQ-10023226](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Serbia/Regulatory-Affairs-Specialist_REQ-10023226)
5. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Serbia/Regulatory-Affairs-Specialist\\_REQ-10023226](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Serbia/Regulatory-Affairs-Specialist_REQ-10023226)