

# Odgovorna oseba za sproščanje zdravil na trg - QP (m/ž/d) / Responsible person for release of medicinal products (QP) (m/f/d)

Job ID  
REQ-10029769  
Nov 14, 2024  
Eslovenia

## Resumen

#LI-Hybrid

Na naši lokaciji v Ljubljani vzpostavljamo nov proizvodni obrat za aseptične izdelke, opremljen z najsodobnejšo tehnologijo, in iščemo sodelavca, ki bo z navdušenjem prevzel odgovornost za sproščanje naših prvih izdelkov na trg leta 2025.

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We are establishing a new Aseptic Production Facility equipped with cutting-edge technology at our Ljubljana site and we are looking for someone excited to take on the responsibility for the release of our first assembled and packaged aseptic products to the market in 2025.

## About the Role

### Vaše ključne odgovornosti:

- Oceno varnosti in kakovosti proizvedenih serij zdravil.
- Sproščanje posameznih serij zdravil /tehnično sproščanje DP bulk in končnih izdelkov.
- Certificiranja serij/sprostitev končnih izdelkov na trg v skladu z dovoljenjem za promet z zdravilom in regulativnimi zahtevami (EU, FDA, lokalna zakonodaja) za izdelke, ki se bodo proizvajali in/ali sestavljali ter pakirali na lokaciji v Ljubljani in Stein-u.
- Letni pregledi kakovosti izdelkov.
- Reševanje zahtevnejših odstopov, reklamacij in vrednotenje predlogov za spremembe.
- Zagotavljanje učinkovitega sistema kakovosti v skladu z Novartisovimi standardi, zakonodajo, dobrimi farmacevtskimi praksami in poslovnimi cilji.
- Dodatne odgovornosti, ki jih dodeli vodja v skladu z letnimi cilji in kazalniki uspešnosti.

### Vaš doprinos k delovnem mestu:

Pričakujemo komunikativne osebe, usmerjene k tinskemu delu in doseganju rezultatov, ki so pripravljene sprejemati nove izzive in stremijo k širitvi svojega znanja.

- Visokošolsko izobrazbo farmacevtske smeri.

- Najmanj 3 leta delovnih izkušenj na vsaj enem od naslednjih področjih v farmacevtski industriji: razvoj, proizvodnja, MS&T, kakovost.
- Prednost predstavljajo izkušnje na področju proizvodnje aseptičnih izdelkov in kontrole kakovosti.
- Aktivno znanje angleškega jezika.

Ponujamo zaposlitev za nedoločen čas s 6-mesečno poskusno dobo. Vljudno vabljeni, da oddate svojo prijavo in življenjepis v angleškem jeziku.

### **Kaj nudimo:**

Konkurenčen plačni paket, letni bonus, fleksibilen način dela, z možnostjo prilagajanja urnika in delom od doma, zaposlitev v podjetju s certifikatom TOP Employer, pokojninsko shemo, shemo nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju telesnega, duševnega in družbenega počutja (Polni življenja) ter dogodke, neomejene priložnosti za učenje in razvoj.

### **Predani smo raznolikosti in vključenosti**

Novartis si prizadeva ustvariti izjemno, vključujoče delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo naše bolnike in skupnosti, ki jih oskrbujemo.

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### **Key Responsibilities:**

- Assessment of the safety and quality of manufactured batches.
- Performing batch release /technical release for DP bulk and aseptic finished products.
- Performing batch certification /release to the market of aseptic finished products in accordance with marketing authorization and regulatory requirements (EU, FDA, local legislation) for products which will be manufactured and/or assembled and packed at both Ljubljana and Stein sites.
- Annual product quality reviews.
- Resolving deviations, complaints and evaluating change requests.
- Establishing and ensuring an effective quality system in accordance with Novartis standards, legislation, good pharmaceutical practices and business objectives.
- Additional responsibilities as assigned by the supervisor, in line with the annual objectives and performance indicators.

### **Essential Requirements:**

We expect communicative people who are oriented towards teamwork, achieving results and problem solving, who are ready to take on new challenges and strive to expand their knowledge.

- Education in the field of pharmacy.
- Minimum 3 years of professional experience in one or more of the following areas in Pharmaceutical Industry: development, production, MS&T or quality.
- Advantage is work experience in the field of quality control, medical device and aseptic production.
- Active knowledge of English language.

We offer permanent employment, with 6 months of probation period. You are kindly invited to submit your application and CV in English language.

### **You'll receive:**

Competitive salary, Annual bonus, Flexible working schedule, tailored to your needs, possibility to work from

home, Pension scheme, Employee Recognition Scheme, Expanded program for the promotion of health in the field of physical, mental and social well-being (Wellbeing), employment at Top SI Employer, Unlimited learning and development opportunities.

### **Commitment to Diversity and Inclusion:**

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

**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

Operations

Business Unit

Innovative Medicines

Ubicación

Eslovenia

Sitio

Ljubljana

Company / Legal Entity

SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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### **Accessibility and accommodation**

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to [diversity.inclusion\\_slo@novartis.com](mailto:diversity.inclusion_slo@novartis.com) and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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