

Vi š ja odgovorna oseba za spro š č anje zdravil na trg (m/ ž /d) / Senior QP (m/f/d)

Job ID
REQ-10068341

12月 18, 2025

Slovenia

摘要

#LI-Hybrid

Lokacija / Location: Ljubljana, Slovenija

Vzpostavljamo novo aseptično proizvodno enoto z najsodobnejšo tehnologijo na naši lokaciji v Ljubljani in iščemo nekoga, ki ga navdušuje priložnost, da v letu 2026 prevzame odgovornost za sproščanje naših aseptičnih izdelkov na trg.

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 aseptic products to the market in 2026.

About the Role

Vaš ključna odgovornosti:

- Odgovornost za odločitve o uporabi serij končnih izdelkov.
- Certifikacija izdelkov v skladu s Prilogo 16.
- Pregled in odobritev odprem končnih izdelkov v karanteni ter osnovne serijske dokumentacije (Master Batch Manufacturing Records), kontrolnih postopkov, analitskih metod, protokolov stabilnosti, letnih pregledov kakovosti izdelkov (APQR), načrtov in poročil o usposabljanju za odgovorne za tehnično sproščanje zdravilnih učinkovin (API), vmesnih in razsutih izdelkov. Dodatno nadzor nad načrtom kakovosti (Quality Plan).
- Sodelovanje pri preiskavah kritičnih reklamacij, rezultatov izven specifikacij (OOS) in izven trenda (OOT), odpoklicev izdelkov ter pri obravnavi eskalacij.
- Pregled kakovostnih pogojev, postopkov obvladovanja sprememb, protokolov/poročil o validaciji procesov, aktivnosti prenosa analitskih metod, reklamacij in letnih poročil.
- Sodelovanje pri izvedbi ocen tveganja, presoj (avditov) in inšpekcijskih pregledov.
- Izvajanje in zagotavljanje usposabljanj s področja dobre proizvodne prakse (GMP).

Vaš doprinos k delovnem mestu:

- Komunikativnost, usmerjenost v timsko delo, doseganje rezultatov in reševanje problemov.
- Pripravljenost na nove izzive ter nenehno širjenje znanja.
- Izobrazba s področja farmacije.
- Najmanj 3 leta delovnih izkušenj na enem ali več od naslednjih področij v farmacevtski industriji: razvoj, proizvodnja, MS&T ali kakovost.
- Prednost: delovne izkušnje na področju kontrole kakovosti, medicinskih pripomočkov in aseptične proizvodnje.
- Aktivno znanje angleškega jezika.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedoločeno čas** poskusno dobo **6 mesecev**. Prijavo oddajte z živiljenjepisomv slovenskem in angleškem jeziku.

Ugodnosti in nagrajevanje:

Konkurenčni plačni paket, letni bonus, fleksibilen načrt dela z možnostjo prilagajanja urnika in delom od doma, pokojninska shema, možnost vključitve v kolektivno zdravstveno zavarovanje, shema nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju fizičnega in duševnega dobrega počutja ter delovne obremenitve (Polni živiljenja), številne priložnosti za učenje in razvoj.

Preberite na špiro č nikda spoznate na č ine s katerimi bomo spodbujali vaš osebn in profesionalni razvoj:

<https://www.novartis.com/careers/benefits-rewards>

Predani smo raznolikosti in vključenosti

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

Zakaj Novartis: Pomagati bolnikom in njihovim družinam zahteva več kot le inovativno znanost. Potrebna je skupnost zavzetih ljudi, kot ste vi.

V Novartisu cenimo sodelovanje, podporo in navdihovanje drug drugega za razvoj prebojnih terapij, ki spreminjajo življenja pacientov.

Ste pripravljeni ustvariti svetlejšo prihodnost skupaj z nami?

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

Pridružite se Novartisu: Ni pravo delovno mesto za vas? Prijavite se v našaš bazo talentov, da ostanete v kontaktu z nami in se seznanite z ustreznimi kariernimi priložnostmi, ko se pojavijo: <https://talentnetwork.novartis.com/network>

Key Responsibilities:

- Decision-making authority on the use of batches of finished products.
- Certification of products in accordance with Annex 16.
- Reviewing and approving the shipment of finished products under quarantine, as well as the Master Batch Manufacturing Records, Control Procedures, Analytical Methods, Stability Protocols, Annual Product Quality Reviews (APQR), training plans, and reports for those responsible for the technical release of APIs, intermediates, and bulk products. Additionally, overseeing the Quality Plan.
- Participating in the investigation of critical complaints, Out-of-Specification (OOS) and Out-of-Trend (OOT) results, product recalls, and escalations.
- Reviewing quality agreements, change controls, process validation protocols/reports, analytical transfer activities, complaints, annual reports.
- Participating in the execution of risk assessments, audits, and inspections.

- Implementing GMP training courses.

Essential Requirements:

- Communicative, team-oriented, results-driven and problem-solving mindset.
- Readiness to take on new challenges and continuously expand knowledge.
- Education in the field of pharmacy.
- Minimum 3 years of professional experience in one or more of the following areas in the pharmaceutical industry: development, production, MS&T or quality.
- Advantage: work experience in the field of quality control, medical devices and aseptic production.
- Active knowledge of English language.

We offer **permanent employment** with **6 months** of probation period. Submit your application with the CV in Slovenian and English language.

Benefits and Rewards:

Competitive salary, Annual bonus, Flexible working schedule, tailored to your needs, possibility to work from home, Pension scheme, possibility of joining collective health insurance scheme, Employee Recognition Scheme, Expanded program for the promotion of health in the field of physical and mental well-being and managing workload (Well-being), 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>

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>

部门

Operations

Business Unit

Quality

地点

Slovenia

站点

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

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

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.inclusionslo@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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