

# Strokovni sodelavec za oskrbo zdravil (m/ž/d) / Associate Expert Drug Supply (m/f/d)

Job ID

REQ-10033091

déc 20, 2024

République de Slovénie

## Résumé

#LI-Onsite

Z veseljem napovedujemo ustanovitev novega obrata klinične proizvodnje v Sloveniji, namenjenega hitrejšemu odkrivanju inovativnih zdravil za bolnike po vsem svetu. Najsodobnejši objekt, ki se nahaja v Biocampusu v Mengšu, nudi izjemno priložnost za sodelovanje, inoviranje in vpliv.

Iščemo navdušene in usposobljene strokovnjake za proizvodni tim. Kot strokovni sodelavec za oskrbo zdravil boste del tima Proizvodnih operacij.

Odgovorni boste predvsem za izvajanje dejavnosti, ki podpirajo proizvodni proces, kot so nadzorovanje okolja, menjave izdelkov, ravnanje z vzorci in zagotavljanje skladnosti procesov z zakonodajo, internimi postopki in zahtevami GxP.

Postanite del dinamičnega tima, ki na novo opredeljuje zdravljenje in prinaša upanje tistim, ki ga najbolj potrebujejo. Pridružite se nam pri oblikovanju prihodnosti varovanja zdravja in pri ustvarjanju pomembnih razlik v življenju bolnikov po vsem svetu. Veselimo se vašega prihoda v naš tim!

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We are thrilled to announce the establishing of new clinical manufacturing facility in Slovenia, dedicated to accelerating the creation of innovative medicines for patients around the globe. This cutting-edge facility, located at Biocampus Mengeš, offers unparalleled opportunities for collaboration, innovation, and impact.

We are currently looking to hire passionate and skilled specialists in the Manufacturing Operations team.

As part of our team, you will be primarily responsible for executing activities that support the production process, like environmental monitoring, product change-over and sample management, and ensuring compliance of processes with regulations as well as company internal procedures and GxP requirements.

Be part of a dynamic team that is reimagining medicine and delivering hope to those who need it most. Join us in shaping the future of healthcare and making a meaningful difference in the lives of patients worldwide. We look forward to welcoming you to our team!

## About the Role

## **Vaše ključne odgovornosti:**

- Delovanje v skladu s standardi za kakovost, etiko, varnost, zdravje, okolje in informacijsko varnost ter zagotavljanje upoštevanja predpisov GxP.
- Sodelovanje z notranjimi (npr. DS, DP, AD, GCS) in zunanji deležniki (npr. čistilna služba, vzdrževalno osebje).
- Sodelovanje pri izmenjavi znanja na delovnem področju. Izobraževanje in usposabljanje začasnih zaposlenih ter zaposlenih, ki se še usposabljaajo. Odgovornost za osebni in strokovni razvoj.
- Sodelovanje pri reševanju izzivov in odpravljanju težav. Prepoznavanje, sporočanje in prispevanje k reševanju odstopanj ter izvajanje korektivnih in preventivnih ukrepov. Uporaba pridobljenih izkušenj.
- Podpiranje notranjih (npr. GGA) in zunanjih presoj (npr. JAZMP).
- Izkazovanje pozitivne delovne etike in pozitivno vplivanje na druge.
- Načrtovanje, organizacija, izvajanje in dokumentiranje dejavnosti kliničnih proizvodnih operacij pod zmernim nadzorom (vzorčenje čistih prostorov, menjave izdelkov, ravnanje z materiali in vzorci, shranjevanje in distribucija).
- Izvajanje, razlaga in poročanje rezultatov validacije/verifikacije čiščenja pod zmernim nadzorom. Izdelava in pregledovanje strokovne dokumentacije (npr. ocene čiščenja in tveganja, tehnična dokumentacija).
- Prejemanje, pravilno shranjevanje in priprava blaga za pošiljanje, izvajanje dodeljenega vzorčenja.
- Odgovornost za urejenost in čistočo na dodeljenih področjih dela in prostorih za delo.

## **Vaš doprinos k delovnem mestu:**

- Srednješolska izobrazba.
- Tekoče znanje slovenščine. Tehnično znanje angleščine.
- Minimalno 1 leto izkušenj na primerljivem delovnem mestu.
- Dobre organizacijske sposobnosti in sposobnosti upravljanja z dokumentacijo, ki zagotavljajo vodenje evidenc v skladu s pravili podjetja.
- Sposobnost natančnega upoštevanja navodil in postopkov.
- Ustrezno poznavanje programske opreme in računalniških orodij.

## **Zaželene izkušnje:**

- Ustrezno strokovno ali tehnično znanje na določenem področju (podpora proizvodnji – npr. vzorčenje za spremljanje okolja).
- Dobro poznavanje dobre proizvodne prakse (GMP) in izkušnje z delom v reguliranem proizvodnem okolju.
- Izkušnje s sistemi za upravljanje z materiali in vzorci (npr. SAP, LIMS).

Z izbranim kandidatom bomo sklenili delovno razmerje za nedoločen čas s poskusno dobo **6 mesecev**. Prijavo oddajte z življenjepisom v slovenskem in 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.

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:**

- Working according to appropriate standards defined for quality, ethics, health, safety, environment, information security, and ensuring compliance to GxP regulations.
- Interacting and collaborating with internal (e.g. DS, DP, AD, GCS) and external stakeholders (e.g. cleaning service, maintenance personnel).
- Actively participating in area of work knowledge exchange. Training and coaching temporary employees and employees under training/education. Responsibility for personal and professional development.
- Assisting in routine and non-routine challenges and troubleshooting. Recognizing, communicating and providing input to the solution of deviations and following corrective and preventive actions. Applying lessons learned.
- Supporting internal (e.g. GGA) and external audits (e.g. JAZMP)
- Showing positive work ethics and influencing others
- Planning, organizing, performing and documenting CxMO activities under moderate supervision (clean utilities and cleanrooms sampling, product change-over, material and sample handling, storage and distribution).
- Execution, interpretation, and reporting of results from cleaning validation/verification activities under moderate supervision. Authoring and reviewing scientific documents (e.g., cleaning and risk assessments, technical documentation).
- Receipt, proper storage, and provision for shipping of goods, performing delegated sampling.
- Responsible for order and cleanliness in assigned task areas and rooms.

### **Essential Requirements:**

- High school education.
- Fluent in Slovene. Technical knowledge of English.
- Minimum 1 year experience in a comparable position.
- Good organization and documentation skills, ensuring records are maintained according to company policies.
- Ability to accurately follow instructions and procedures.
- Adequate knowledge of software and computer tools.

### **Desirable Requirements:**

- Adequate scientific or technical knowledge in a specific area (production support – sampling for e.g. environmental monitoring)
- Solid knowledge of GMP and experience working in a regulated manufacturing environment.
- Experience in material and sample management systems (e.g. SAP, LIMS).

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

Division

Development

Business Unit

Innovative Medicines

Emplacement

République de Slovénie

Site

Mengeš

Company / Legal Entity

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

Functional Area

Recherche & Développement

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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