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

Job ID
REQ-10051813

8月 20, 2025

Slovenia

摘要

#LI-Onsite

Z veseljem napovedujemo ustanovitev novega obrata klini č ne proizvodnje v Sloveniji, namenjenega hitrej š emu odkrivanju inovativnih zdravil za bolnike po vsem svetu. Najsodobnej š i objekt, ki se nahaja v Biocampusu v Meng š u, nudi izjemno prilo ž nost za sodelovanje, inoviranje in vpliv.

I š č emo navdu š ene in usposobljene strokovnjake za tim Klini č ne proizvodnje zdravilnih u č inkovin.

Kot strokovni sodelavec za oskrbo zdravil boste odgovorni za izvajanje in dokumentiranje proizvodnega procesa zdravilnih u č inkovin ter za dokumentiranje proizvodnih procesov GMP za zagotavljanje pravo č asne dostave zdravilnih u č inkovin. Sodelovali boste v ve č funkcijskem timu, ki ga koordinirajo izku š eni č lani tima. Odgovorni boste tudi za izvajanje aktivnosti, povezanimi z rednimi validacijami procesov, š tudijami pretoka zraka z uporabo dima, validacijami postopkov č i š č enja in kvalifikacijo opreme.

Postanite del dinami č nega tima, ki na novo opredeljuje zdravljenje in prina š a upanje tistim, ki ga najbolj potrebujejo. Pridru ž ite se nam pri oblikovanju prihodnosti varovanja zdravja in pri ustvarjanju pomembnih razlik v ž ivljenju bolnikov po vsem svetu. Veselimo se va š ega prihoda v na š 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 Menge š , offers unparalleled opportunities for collaboration, innovation, and impact.

We are currently looking to hire passionate and skilled specialists in the Drug substance production team.

As part of our team, you will be primarily responsible for executing and documenting Drug substance manufacturing process and documenting GMP manufacturing processes for a timely delivery of drug substances in collaboration with a multifunctional team coordinated by experienced team members. You will also be responsible for performing activities related to periodic processes validation, smoke studies, cleaning validation procedures and equipment qualifications.

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

Va š **e klju** č **ne odgovornosti:**

- Proizvodnja zdravilnih u č inkovin z nizkim biolo š kim bremenom in sterilnih zdravil za potrebe klini č ne oskrbe, skladna s standardi GxP za klini č no oskrbo, vklju č no z izvajanjem medprocesne kontrole in kontrole poteka procesa ter vpisovanjem v kontrolni sistem.
- Vodenje dokumentacije in nadzor nad izvedenimi aktivnostmi v skladu s standardi GxP (dokumentacija proizvodnih serij, vodenje dnevnika, oznake, obrazci, druge zahtevane priloge).
- Priprava, izdajanje, izpolnjevanje in arhiviranje dokumentacije (dnevniki, obrazci, dokumentacija proizvodnih serij, itd.), pregled in preverjanje neobdelanih podatkov, ki so jih pripravili drugi. Zapis enostavnih postopkov, protokolov in poro č il pod zmernim nadzorom (delovni postopki, poro č ila o trendih, itd.)
- Prevzemanje odgovornosti za uporabo orodij, opreme ali specializiranih prostorov pod nadzorom; izvajanje kvalifikacije opreme, sestavljanje in razstavljanje opreme. Zagotavljanje razpolo ž ljivosti dodeljene opreme.
- Delovanje v skladu s standardi za kakovost, etiko, varnost, zdravje, okolje in informacijsko varnost ter zagotavljanje upo š tevanja predpisov GxP.
- Sodelovanje pri re š evanju izzivov in odpravljanju te ž av. Prepoznavanje, sporo č anje in prispevanje k re š evanju odstopanj ter izvajanje korektivnih in preventivnih ukrepov. Uporaba pridobljenih izku š enj.
- Podpiranje notranjih (npr. GGA) in zunanjih presoj (npr. JAZMP).Sodelovanje pri izmenjavi znanja na delovnem podro č ju.Odgovornost za osebni in strokovni razvoj.

- Izkazovanje pozitivne delovne etike in pozitivno vplivanje na druge.

Va š **doprinos k delovnem mestu:**

- Srednje š olska izobrazba.
- Teko č e znanje sloven š č ine. Tehni č no znanje angle š č ine.
- Minimalno 1 leto izku š enj na primerljivem delovnem mestu.
- Dobro poznavanje laboratorijskih, proizvodnih in/ali tehni č nih orodij.
- Dobre organizacijske sposobnosti in sposobnosti upravljanja z dokumentacijo, ki zagotavljajo vodenje evidenc v skladu s pravili podjetja.
- Zavedanje o varnem ravnanju s kemikalijami, potencialno nevarnimi materiali in opremo. Sposobnost natan č nega upo š tevanja navodil in postopkov.
- Ustrezno poznavanje programske opreme in ra č unalni š kih orodij.

Za ž **elene izku** š **nje:**

- Ustrezno strokovno ali tehni č no znanje na dolo č enem podro č ju (proizvodnja zdravilnih u č inkovin).
- Dobro poznavanje dobre proizvodne prakse (GMP) in izku š nje z delom v reguliranem proizvodnem okolju ter izku š nje s sistemi za upravljanje z materiali in vzorci (npr. SAP, LIMS).

Z izbranim kandidatom bomo sklenili delovno razmerje za nedolo č en č as. Prijavo oddajte z ž ivljenjepisom v slovenskem in angle š kem jeziku.

Kaj nudimo:

Konkuren č en pla č ni paket, letni bonus, fleksibilen na č in dela, z mo ž nostjo prilagajanja urnika in delom od doma, pokojninsko shemo, shemo nagrajevanja in priznanja dose ž kov, raz š irjeni program promocije zdravja na podro č ju telesnega, du š evnega in dru ž benega po č utja (Polni ž ivljenja) ter dogodke, neomejene prilo ž nosti za u č enje in razvoj.

Predani smo raznolikosti in vklju č **enosti**

Novartis si prizadeva ustvariti izjemno, vklju č ujo č e delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo na š e bolnike in skupnosti, ki jih oskrbujemo.

Key Responsibilities:

- GxP-compliant production low bio-burden drug substance and sterile medicinal product for clinical supply, including execution of in-process (IPC) or process flow controls and input into the controlling system.
- GxP-compliant documentation and control of activities carried out (batch documentation,

logbooks, labels, forms, associated enclosures).
- Providing, issuing, filling-out and archiving documentation (logbooks, forms, batch records, etc.). Reviewing and verifying raw data generated by others. Writing simple procedures, protocols and reports under moderate supervision (work procedures, trending reports, etc.).
- Taking over responsibility for and utilizing tools, equipment, or specialized facilities under supervision; executing equipment qualification and equipment assembly and disassembly. Responsible for ensuring the availability of assigned equipment.Working according to appropriate standards defined for quality, ethics, health, safety, environment, information security, and ensuring compliance to GxP regulations.
- Actively participating in area of work knowledge exchange. 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.

Essential Requirements:

- High school education
- Fluent in Slovene. Technical knowledge of English
- Minimum 1 year experience in a comparable position
- Good knowledge of laboratory, plant, and/or technical tools.
- Good organization and documentation skills, ensuring records are maintained according to company policies.
- Awareness for safe handling of chemicals, potentially dangerous materials, and equipment. Ability to accurately follow instructions and procedures.
- Adequate knowledge of software and computer tools.

We offer **permanent employment**. 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 (Energized for Life), 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

部门
Development

Business Unit
Innovative Medicines

地点
Slovenia

站点
Menge š

Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

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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