Višji ekspert za oskrbo zdravil (m/ž/d) / Senior Expert Drug Supply (m/f/d)

Job ID
REQ-10034729
Dec 20, 2024
Slovenia

Summary

#LI-Hybrid

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 production team.
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!
As part of our team, you will be primarily responsible ensuring sterility assurance and contamination control in the Clinical Manufacturing Plant
As Senior Expert Drug Supply you will be part of the DP Clinical Manufacturing Team at our TRD site in Menges, Slovenia.

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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.
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!
Kot del tima boste odgovorni predvsem za zagotavljanje sterilnosti in za nadzor nad kontaminacijo v obratu klinične proizvodnje.
Kot Višji ekspert za oskrbo zdravil boste del tima Klinične proizvodnje zdravil na naši lokaciji TRD v Mengšu, Slovenija.

About the Role

Key Responsibilities:

- Sterility assurance and contamination control within the Clinical Manufacturing Plant.
- Investigation of microbiological related deviations / OOX, conducting root cause analysis, and implementation of CAPAs and corresponding Risk Assessment.

- Contribution in the preparation and execution of validations (clean room validation, aseptic process validation), including process and environmental monitoring.
- Providing technical expertise during regulatory inspections and ensuring compliance with regulatory requirements.
- Developing and improving cleaning, sanitation, and environmental monitoring programs.
- Cross-Functional Collaboration to align activities with organizational goals.
- Mentoring and providing technical guidance to junior team members.
- Utilizing data analytics, machine learning, and artificial intelligence to optimize performance parameters.
- Proactive review and improvement of aseptic programs and contamination control strategies.

Essential Requirements:

- Accountability: responsibility for assigned tasks and reliability.
- Decision Making: correct interpretation of analyses and evaluations and identifying appropriate measures to be taken.
- Ability to work in a team (constructive and reliable contribution in a group setting) and in a matrix environment. Influencing without authority.
- Results driven self-motivation and motivation of others to achieve outstanding results while ensuring adherence to ethical and legal principles, with a continuous drive for improvement.
- Customer focus as the highest priority.
- Quality focus: providing the highest quality products and services that meet the needs and requirements of internal and external customers.
- Significant experience in CMC development and/or production.
- 5 years of experience in Pharmaceutical Industry and 3 years of Microbiological Experience; thorough knowledge of cGMP requirements.

Desirable Requirements:

- 2 years of experience within Manufacturing QA.
- Knowledge of Slovenian Language.

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.

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Vaše ključne odgovornosti:

- Zagotavljanje sterilnosti in nadzora nad kontaminacijo v obratu klinične proizvodnje.
- Raziskovanje mikrobioloških odstopanj / OOX, izvajanje analize temeljnih vzrokov ter izvajanje CAPA in ustreznih ocen tveganja.
- Sodelovanje pri pripravi in izvedbi validacij (validacija čistih prostorov, validacija aseptičnih postopkov), vključno z monitoriranjem procesov in okolja.
- Tehnična podpora med regulativnimi inšpekcijami in zagotavljanje skladnosti z regulativnimi zahtevami.
- Razvoj in izboljšava programov čiščenja, sanacije in monitoringa okolja.
- Medsektorsko sodelovanje za uskladitev dejavnosti s cilji organizacije.
- Mentorstvo in tehnične usmeritve mlajšim članom ekipe.
- Uporaba podatkovne analitike, strojnega učenja in umetne inteligence za optimizacijo parametrov zmogljivosti.
- Proaktivno pregledovanje in izboljševanje aseptičnih programov in strategij za nadzor kontaminacije.

Vaš doprinos k delovnem mestu:

- Prevzemanje odgovornosti za svoje naloge in zanesljivost.
- Sprejemanje odločitev: pravilna interpretacija analiz in vrednotenj ter prepoznavaje potrebnih ukrepov.
- Sposobnost timskega dela (konstruktivno in zanesljivo delovanje v skupini) in delovanja v matričnem okolju ter vplivanje brez avtoritete.
- Usmerjenost k rezultatom: samo-motivacija in motivacija sodelavcev za doseganje rezultatov, zagotavljanje spoštovanja etičnih in pravnih načel ter nenehno prizadevanje za izboljšave.
- Osredotočenost na stranke.
- Osredotočenost na kakovost: zagotavljanje kakovostnih izdelkov in storitev, ki izpolnjujejo potrebe in zahteve notranjih in zunanjih strank.
- Ustrezne izkušnje pri razvoju in proizvodnji CMC.
- 5 let izkušenj v farmacevtski industriji in 3 leta izkušenj s področja mikrobiologije; dobro poznavanje zahtev cGMP.

Zaželene izkušnje:

- 2 leti izkušenj na področju zagotavljanja kakovosti (QA) v proizvodnji.
- Znanje slovenskega jezika.

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.

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.

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
Location
Slovenia
Site
Mengeš
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.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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