Vi š ji ekspert za oskrbo zdravil (poudarek na strategiji zagotavljanja sterilnosti/obvladovanja kontaminacije) (m/ ž /d) / Senior Expert Drug Supply (Focus -Sterility Assurance/Contamination Control Strategy) (m/f/d)

Job ID
REQ-10034729

2月 10, 2025

Slovenia

摘要

#LI-Hybrid

Z navdu š enjem sporo č amo, da ustanavljamo novo klini č no proizvodno enoto v Sloveniji, namenjeno pospe š evanju ustvarjanja inovativnih zdravil za paciente po celem svetu.

Kot Vi š ji ekspert za oskrbo zdravil boste del na š e ekipe za klini č no proizvodnjo zdravil na na š i tehni č ni raziskovalni in razvojni lokaciji v Meng š u, Slovenija, in boste glavna odgovorna oseba za zagotavljanje sterilnosti in obvladovanje kontaminacije v klini č ni proizvodnji.

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.

As Senior Expert Drug Supply you will be part of our Drug Product Clinical Manufacturing Team at our Technical Research and Development site in Menge š , Slovenia and be primarily responsible for ensuring sterility assurance and contamination control at the Clinical Manufacturing Plant.

About the Role

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

- Zagotavljanje sterilnosti in obvladovanje kontaminacije v klini č ni proizvodnji.
- Preiskovanje mikrobiolo š kih odstopanj / OOX, izvajanje analize koreninskih vzrokov ter izvajanje ukrepov CAPA in ustrezne ocene tveganja.
- Sodelovanje pri pripravi in izvedbi validacij (validacija č istih prostorov, asepti č nega procesa), vklju č no s procesnim in okoljskim spremljanjem.
- Zagotavljanje tehni č nega strokovnega znanja med regulatornimi in š pekcijami ter skladnost z zakonodajnimi zahtevami.
- Razvijanje in izbolj š anje programov č i š č enja, sanitacije in okoljskega spremljanja.
- Sodelovanje med razli č nimi oddelki za usklajevanje dejavnosti z organizacijskimi cilji.
- Mentorstvo in zagotavljanje tehni č nega vodstva mlaj š im č lanom ekipe.
- Uporaba analize podatkov, strojnega u č enja in umetne inteligence za optimizacijo mejnikov uspe š nosti.
- Proaktivno pregledovanje in izbolj š evanje asepti č nih programov ter strategij za obvladovanje kontaminacije.

Va š **doprinos k delovnem mestu:**

- Odgovornost za dodeljene naloge in zanesljivost.
- Odlo č anje: pravilna interpretacija analiz in evalvacij ter identifikacija ustrezni ukrepov.
- Zmo ž nost dela v ekipi (konstruktiven in zanesljiv prispevek v skupinskih okoljih) ter v matri č nem okolju. Vplivanje brez formalne avtoritete.
- Samomotivacija za dosego rezultatov ter motivacija drugih za doseganje izjemnih rezultatov ob hkratnem zagotavljanju upo š tevanja eti č nih in zakonitih na č el ter stalnem prizadevanju za izbolj š anje.
- Zmo ž nost postavljanja fokusa na stranko kot glavno prioriteto.
- Poudarek na kakovosti: zagotavljanje izdelkov in storitev najvi š je kakovosti, ki ustrezajo potrebam in zahtevam internih in eksternih strank.
- Pomembne izku š nje na podro č ju razvoja in/ali proizvodnje u č inkovin.
- 5 let izku š enj v farmacevtski industriji in 3 leta izku š enj na podro č ju mikrobiologije; temeljito poznavanje zahtev cGMP.

Za ž **elene izku** š **nje:**

- 2 leti izku š enj na podro č ju kakovosti proizvodnje.
- Znanje slovenskega jezika.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedolo** č **en** č **as** posko usno dobo **6 mesecev**.

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:

- 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), 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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