

Višji 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

fév 03, 2025

République de Slovénie

Résumé

#LI-Hybrid

Z navdušenjem sporočamo, da ustanavljamo novo klinično proizvodno enoto v Sloveniji, namenjeno pospeševanju ustvarjanja inovativnih zdravil za paciente po celem svetu.

Kot Višji ekspert za oskrbo zdravil boste del naše ekipe za klinično proizvodnjo zdravil na naši tehnični raziskovalni in razvojni lokaciji v Mengšu, Slovenija, in boste glavna odgovorna oseba za zagotavljanje sterilnosti in obvladovanje kontaminacije v klinični 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 Mengeš, Slovenia and be primarily responsible for ensuring sterility assurance and contamination control at the Clinical Manufacturing Plant.

About the Role

Vaše ključne odgovornosti:

- Zagotavljanje sterilnosti in obvladovanje kontaminacije v klinični proizvodnji.
- Preiskovanje mikrobioloških odstopanj / OOX, izvajanje analize koreninskih vzrokov ter izvajanje ukrepov CAPA in ustrezne ocene tveganja.
- Sodelovanje pri pripravi in izvedbi validacij (validacija čistih prostorov, aseptičnega procesa), vključno s procesnim in okoljskim spremljanjem.
- Zagotavljanje tehničnega strokovnega znanja med regulatornimi inšpekcijami ter skladnost z zakonodajnimi zahtevami.
- Razvijanje in izboljšanje programov čiščenja, sanitacije in okoljskega spremljanja.

- Sodelovanje med različnimi oddelki za usklajevanje dejavnosti z organizacijskimi cilji.
- Mentorstvo in zagotavljanje tehničnega vodstva mlajšim članom ekipe.
- Uporaba analize podatkov, strojnega učenja in umetne inteligence za optimizacijo mejnikov uspešnosti.
- Proaktivno pregledovanje in izboljševanje aseptičnih programov ter strategij za obvladovanje kontaminacije.

Vaš doprinos k delovnem mestu:

- Odgovornost za dodeljene naloge in zanesljivost.
- Odločanje: pravilna interpretacija analiz in evalvacij ter identifikacija ustreznih ukrepov.
- Zmožnost dela v ekipi (konstruktiven in zanesljiv prispevek v skupinskih okoljih) ter v matričnem okolju. Vplivanje brez formalne avtoritete.
- Samomotivacija za doseganje rezultatov ter motivacija drugih za doseganje izjemnih rezultatov ob hkratnem zagotavljanju upoštevanja etičnih in zakonitih načel ter stalnem prizadevanju za izboljšanje.
- Zmožnost postavljanja fokusa na stranko kot glavno prioriteto.
- Poudarek na kakovosti: zagotavljanje izdelkov in storitev najvišje kakovosti, ki ustrezajo potrebam in zahtevam internih in eksternih strank.
- Pomembne izkušnje na področju razvoja in/ali proizvodnje učinkovin.
- 5 let izkušenj v farmacevtski industriji in 3 leta izkušenj na področju mikrobiologije; temeljito poznavanje zahtev cGMP.

Zaželene izkušnje:

- 2 leti izkušenj na področju kakovosti proizvodnje.
- 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, 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.

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>

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 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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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