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

Job ID
REQ-10033083
Dec 20, 2024
Slovenia

Summary

#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 tim Klinične proizvodnje zdravilnih učinkovin.

Kot strokovni sodelavec za oskrbo zdravil boste odgovorni za izvajanje in dokumentiranje proizvodnega procesa zdravilnih učinkovin ter za dokumentiranje proizvodnih procesov GMP za zagotavljanje pravočasne dostave zdravilnih učinkovin. Sodelovali boste v večfunkcijskem timu, ki ga koordinirajo izkušeni člani tima. Odgovorni boste tudi za izvajanje aktivnosti, povezanimi z rednimi validacijami procesov, študijami pretoka zraka z uporabo dima, validacijami postopkov čiščenja in kvalifikacijo opreme.

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 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

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 zunanjimi deležniki (npr. čistilna služba, vzdrževalno osebje).
- Sodelovanje pri izmenjavi znanja na delovnem področju. Izobraževanje in usposabljanje začasnih zaposlenih ter zaposlenih, ki se še usposabljajo. 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.

- Proizvodnja zdravilnih učinkovin z nizkim biološkim bremenom in sterilnih zdravil za potrebe klinične oskrbe, skladna s standardi GxP za klinično oskrbo, vključno 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 poročil pod zmernim nadzorom (delovni postopki, poročila o trendih, itd.)
- Prevzemanje odgovornosti za uporabo orodij, opreme ali specializiranih prostorov pod nadzorom; izvajanje kvalifikacije opreme, sestavljanje in razstavljanje opreme. Zagotavljanje razpoložljivosti dodeljene opreme.

Vaš doprinos k delovnem mestu:

- Srednješolska izobrazba.
- Tekoče znanje slovenščine. Tehnično znanje angleščine.
- Minimalno 1 leto izkušenj na primerljivem delovnem mestu.
- Dobro poznavanje laboratorijskih, proizvodnih in/ali tehničnih 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 natančnega upoštevanja navodil in postopkov.
- Ustrezno poznavanje programske opreme in računalniških orodij.

Zaželene izkušnje:

- Ustrezno strokovno ali tehnično znanje na določenem področju (proizvodnja zdravilnih učinkovin).
- 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.

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.

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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
- 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.

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.

Desirable Requirements:

- Adequate scientific or technical knowledge in a specific area (manufacturing of drug substance)
- 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

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Business Unit
Innovative Medicines
Location
Slovenia
Site
Mengeš
Company / Legal Entity
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Functional Area
Research & Development
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.

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