Skrbnik GMP za oskrbo zdravil (m/ ž /d) / GMP Officer Drug Supply (m/f/d)

Job ID
REQ-10046571

4月 02, 2025

Slovenia

摘要

#LI-Hybrid ALI

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 na na š i lokaciji TRD v Meng š u, Slovenija.

Kot Skrbnik dobre proizvodne prakse za oskrbo zdravil boste odgovorni predvsem za za strate š ko vodenje izvajanja konceptov kakovosti v klini č ni proizvodnji. Delali boste neposredno z vodstvenim timom klini č ne proizvodnje ter s posameznimi strokovnjaki iz podro č ja.

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. Our new 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 Clinical Manufacturing Team at our TRD site in Menge š , Slovenia.

As GMP Officer Drug Supply, you will be responsible for strategically driving the implementation of quality concepts within Clinical Manufacturing. You will be working directly with the Clinical Manufacturing Leadership Team as well as Experts.

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:**

- Vzpostavitev in vzdr ž evanje sistema upravljanja dobre proizvodne prakse (GMP) v klini č ni proizvodnji ter spremljanje skladnosti z notranjimi in zunanjimi predpisi.
- Svetovanje in podpora vodji in zaposlenim klini č ne proizvodnje pri vpra š anjih, povezanih z dobro proizvodno prakso. Redno in pogosto obve š č anje vodstvenega tima o napredku, uspehih in razvojnih potrebah programa, vklju č no z ovirami.
- Nadzorovanje vseh aktivnosti dobre proizvodne prakse v klini č ni proizvodnji in usklajevanje letne posodobitve ustreznih dokumentov (npr. glavna dokumentacija o lokaciji, glavni na č rt validacije (č i š č enja), poro č ila o trendih).
- Priprava tima in aktivno sodelovanje pri presojah GMP, vklju č no z organizacijo in usklajevanjem dejavnosti pred in po presoji. Vodenje linijske funkcije pri notranjih in zunanjih presojah kakovosti.
- Oblikovanje programov usposabljanja GMP za zaposlene v klini č ni proizvodnji v sodelovanju z drugimi funkcijami, zagotavljanje ustreznega usposabljanja in njegove izvedbe. Vodenje sistemskih sprememb in odstopanj s spremljanjem upravljanja zapisov, usposabljanjem odgovornih za odstopanja in podpiranjem pravo č asnega dokon č anja zapisov.

Va š **doprinos k delovnem mestu:**

- Najmanj 5 let ustreznih izku š enj na primerljivem delovnem mestu (zagotavljanje kakovosti, skladnost s kakovostjo, nadzor kakovosti, asepti č na proizvodnja).

- Univerzitetna diploma iz farmacevtske tehnologije, biokemije, kemijskega in ž eniringa ali druge ustrezne naravoslovne smeri.

- Dobro razumevanje razvojnih procesov NBE in NCE ter ustreznih vmesnikov za prenos na klini č no proizvodnjo.
- Dobro poznavanje zahtev GMP in njihove uporabe.
- Teko č e znanje slovenskega in angle š kega jezika.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedolo** č **en** č **as** poskusno 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:

- Establishes and maintains CM GMP management system and monitors compliance with internal and external regulations.
- Advises and supports CM head and CM staff regarding GMP issues; Keeps senior leadership fully involved through frequent communication on the program ' s progress, successes, and development needs including roadblocks and bottlenecks.
- Oversees all GMP activities within CM and coordinates the yearly update of appropriate documents (e.g. Site Master File, (Cleaning) Validation Master Plan and Trending reports).
- Preparing a team and actively participating in GMP assessments, including organizing and coordinating pre- and post-audit activities. Line function lead in internal and external Quality audits and inspections.
- Designs GMP training programs for CM staff in coordination with other functions and ensures that sufficient and appropriate training is provided and completed; Is the System Change and Deviation champion through monitoring record management, coaching of deviation owners and supports timely completion of records.

Essential Requirements:

- Minimum 5 years of relevant experience in comparable position (Quality Assurance, Quality Compliance, Quality Control, Aseptic Manufacturing).
- University degree in pharmaceutical technology, biochemistry, chemical engineering or other relevant natural sciences.
- Profound understanding of Development processes of NBEs and NCEs and the relevant

interfaces for transfer to Clinical Manufacturing.
- Profound knowledge of GMP requirements and its applications.
- Fluent in English and Slovene.

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 (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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