Odgovorna oseba za spro š č anje zdravil na trg / QP

Job ID
REQ-10052802

8月 01, 2025

Slovenia

摘要

#LI-Hybrid
Lokacija: Menge š , Slovenija

Novartis se podaja na navdihujo č o novo pot proizvodnje celi č ne in genske terapije in i š č e izjemno motivirane posameznike, ki se nam bodo pridru ž ili na tej poti k odli č nosti. I š č emo strastne zaposlene, ki so pripravljeni prispevati svoj talent in soustvarjati na š uspeh. To je izjemna prilo ž nost za sodelovanje v dinami č nih ekipah in soustvarjanje prihodnosti. V Novartisu i š č emo odgovorno osebo za spro š č anje inovativnih biolo š kih in genskih zdravil na trg, s klju č no vlogo pri zagotavljanju skladnosti z zakonodajo in standardi kakovosti, ki bo omogo č ala nemoteno oskrbo pacientov z zdravili. Č e vas navdihuje delo z neposrednim vplivom na zdravje in ž ivljenja ljudi in ste oseba zavezana osebni odli č nosti z visokim nivojem integritete ter si ž elite poklicno in osebno rasti v dinami č nem delovnem okolju, vas vabimo, da se nam pridru ž ite.

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Novartis is embarking on an inspiring new journey in cell and gene therapy manufacturing and is looking for highly motivated individuals to join us on this path to excellence. We are seeking passionate employees who are ready to contribute their talent and co-create our success. This is an exceptional opportunity to work in dynamic teams and help shape the future.

At Novartis, we are looking for a responsible person to release innovative biological and gene therapies to the market, playing a key role in ensuring compliance with legislation and quality standards, thereby enabling uninterrupted patient access to medicines.

If you are inspired by work that has a direct impact on people ' s health and lives, and you are committed to personal excellence with a high level of integrity, and wish to grow professionally and personally in a dynamic work environment, we invite you to join us.

About the Role

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

- Spro š č anje inovativnih biolo š kih in genskih zdravil na trg skladno z direktivami EU, FDA ter lokalno zakonodajo, dolo č ili pogodb s partnerji in internimi postopki.
- Pregledovanje, preverjanje in ocenjevanje proizvodne ter analitske dokumentacije.
- Razvoj notranjega sistema kakovosti v skladu z dobro proizvodno prakso, zakonodajo in standardi Novartisa.
- Raziskovanje odstopanj v proizvodnji zdravil in predlaganje korektivnih ter preventivnih ukrepov.
- Priprava in revidiranje dokumentacije za nadzor kakovosti izdelkov.
- Obvladovanje reklamacij, potrjevanje letnih pregledov kakovosti, sprememb in izbolj š av.

Va š **doprinos k delovnem mestu:**

- Visoko š olska izobrazba farmacevtske ali naravoslovne smeri
- Najmanj 3 leta izku š enj na podro č ju spro š č anja zdravil
- Dobro poznavanje slovenske zakonodaje o zdravilih
- Aktivno znanje angle š kega jezika (pisno in ustno)
- Uporabni š ko znanje orodij Microsoft Office
- Zavezanost osebnemu in strokovnemu razvoju

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

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, zaposlitev v podjetju s certifikatom TOP Employer, pokojninsko shemo, shemo nagrajevanja in priznanja dose ž kov, raz š irjeni program promocije zdravja na podro č ju telesnega,

du š evnega indru ž benega po č utja (Polni ž ivljenja) ter dogodki in 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.

Dostop in prilagoditve

V Novartisu si prizadevamo k vklju č enosti oseb z invalidnostjo in zagotavljanju ustreznih prilagoditev delovnega okolja posameznikom z omejitvami. V kolikor zaradi bolezni ali invalidnosti potrebujete ustrezne prilagoditve v kateremkoli delu selekcijskega procesa oziroma potrebujete prilagoditve pri izvajanju osnovnih nalog na delovnem mestu, nam pi š ite na naslov diversity.inclusionslo@novartis.com in navedite, kak š ne prilagoditve potrebujete ter va š e kontaktne podatke. Prosimo, vklju č ite tudi podatek o š tevilki razpisa, na katerega se prijavljate.

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Your Key Responsibilities:

- Releasing innovative biological and gene therapies to the market in accordance with EU directives, FDA regulations, local legislation, partner agreements, and internal procedures.
- Reviewing, verifying, and evaluating manufacturing and analytical documentation.
- Developing the internal quality system in line with Good Manufacturing Practices (GMP), legislation, and Novartis standards.
- Investigating deviations in drug manufacturing and proposing corrective and preventive actions.
- Preparing and revising product quality control documentation.
- Managing complaints, approving annual product quality reviews, changes, and improvements.

Your Contribution to the Role:

- University degree in pharmacy or a natural science discipline.
- At least 3 years of experience in drug release processes.
- Good knowledge of Slovenian pharmaceutical legislation.
- Proficiency in English (written and spoken).
- Proficient in Microsoft Office tools.
- Commitment to personal and professional development.

The selected candidate will be offered a **permanent employment contract** with a 6-month probation period.

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.

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.

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
Operations

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
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

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