Vi š ji strokovnjak za podro č je vizualne kontrole (m/ ž /d) / Senior Visual Inspection Expert (m/f/d)

Job ID
REQ-10055757

7月 29, 2025

Slovenia

摘要

#LI-Hybrid

Z navdu š enjem napovedujemo ustanovitev novega klini č nega proizvodnega obrata v Sloveniji, ki bo namenjen pospe š evanju ustvarjanja inovativnih zdravil za bolnike po vsem svetu. Ne zamudite prilo ž nosti, da se pridru ž ite na š i mednarodni ekipi.

Kot vi š ji strokovnjak za vizualni pregled oskrbe z zdravili boste del na š e ekipe za klini č no proizvodnjo zdravil na na š i lokaciji za tehni č ne raziskave in razvoj v Meng š u v Sloveniji in boste primarno odgovorni za zagotavljanje pripravljenosti za vizualni pregled in kakovosti zdravil v klini č nem proizvodnem obratu.

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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. Don ’ t miss the chance to join our international team.

As Senior Visual Inspection Expert Drug Supply you will be part of our Drug Product Clinical Manufacturing Team Technical Research and Development site in Menge š , Slovenia and be primarily responsible for ensuring visual inspection readiness and drug product quality at the Clinical Manufacturing Plant.

About the Role

Va š **e klju** č **ne odgovornosti**

- Uvajanje in vzdr ž evanje regulativnih in notranjih zahtev, povezanih z vizualnim pregledom kon č nega izdelka, proizvedenega v proizvodnji zdravila, ki zagotavljajo varnost pacientov in kakovosti zdravil.
- Vodenje usposabljanja za sodelavce, ki izvajajo vizualno kontrolo.
- Priprava in vzdr ž evanje knji ž nice napak.
- Zagotavljanje podpore sodelavcem, ki izvajajo vizualno kontrolo proizvedenih serij v proizvodnji.
- Evaluacija ustreznosti metode za vizualno kontrolo (GMP ocena tveganja) novih izdelkov in usposabljanje sodelavcev za vizualni pregled o posebnostih.
- Vodenje odstopov povezanih z vizualnim pregledom in OOX ter izvajanje CAPA.
- Vzdr ž evanje baze podatkov in zagotavljanje rezultatov, povezanih z vizualnim pregledom proizvedenega zdravila.
- Soustvarjanje zahtev in sodelovanje pri pripravi dokumentacije (SOP) povezane s podro č jem vizualne kontrole znotraj celotnega podjetja in izvajanje skladno z zahtevami in posebnostmi proizvodnje klini č nih zdravil.
- Zagotavljanje tehni č nega in strokovnega znanja med in š pekcijskimi pregledi in zagotavljanje skladnosti z regulativnimi zahtevami.
- Proaktivne revizije in izbolj š anje strategij povezanih s podro č jem vizualnega pregleda zdravila v proizvodnji klini č nih zdravil.

Va š **doprinos k delovnemu mestu:**

- Odgovornost za dodeljene naloge in zanesljivost.
- Odlo č anje: pravilna interpretacija analiz in rezultatov testiranj ter predlaganje in uvajanje korektivnih ukrepov.
- Sposobnost dela v skupini (konstruktiven in zanesljiv prispevek) in delovanje tako v skupini kot v matri č nem okolju. Vplivanje brez avtoritete.
- Delovanje, ki temelji na rezultatih, in motiviranje sodelavcev za doseganje izjemnih rezultatov, hkrati pa zagotavlja spo š tovanje eti č nih in pravnih na č el, z nenehnim prizadevanjem za izbolj š ave.
- Vzpostavljanje in vzdr ž evanje trdnih odnosov s poslovnimi partnerji.
- Osredoto č enost na kakovost: zagotavljanje izdelkov in storitev najvi š je kakovosti, ki ustrezajo potrebam pacientov ter zahtevam notranjih in zunanjih partnerjev.
- Pomembne izku š nje z razvojem in/ali proizvodnjo zdravil.
- 5 let izku š enj v farmacevtski industriji in 3 leta izku š enj z vizualnim pregledom / karakterizacijo delcev ali druge ustrezne izku š nje; temeljito poznavanje zahtev cGMP.

Ponujamo **stalno zaposlitev** s **6-mese** č **no**poskusno dobo. Oddajte svojo prijavo z ž ivljenjepisom v angle š kem jeziku.

Ugodnosti in nagrajevanje: Konkuren č en pla č ni paket, letni bonus, fleksibilen na č in dela z mo ž nostjo prilagajanja urnika in delom od doma, pokojninska shema, shema nagrajevanja in priznanja dose ž kov, raz š irjeni program promocije zdravja na podro č ju telesnega, du š evnega in fizi č nega po č utja (iniciativa Polni ž ivljenja), š tevilne prilo ž nosti za u č enje in razvoj.

Preberite na š priro č nik, da spoznate na č ine, s katerimi bomo spodbujali va š osebni in profesionalni razvoj: https://www.novartis.com/careers/benefits-rewards

Zakaj Novartis: Pomagati bolnikom in njihovim dru ž inam zahteva ve č kot le inovativno znanost. Potrebna je skupnost zavzetih ljudi, kot ste vi. V Novartisu cenimo sodelovanje, podporo in navdihovanje drug drugega za razvoj prebojnih terapij, ki spreminjajo ž ivljenja pacientov. Ste pripravljeni ustvariti svetlej š o prihodnost skupaj z nami?
https://www.novartis.com/about/strategy/people-and-culture

Pridru ž ite se Novartisu: Ni pravo delovno mesto za vas? Prijavite se v na š o bazo talentov, da ostanete v kontaktu z nami in se seznanite z ustreznimi kariernimi prilo ž nostmi takoj, ko se pojavijo: https://talentnetwork.novartis.com/network

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.

Key Responsibilities:

- Implementation and maintenance of visual inspection related regulatory and internal requirements within the Clinical Drug Product Manufacturing assuring patient safety and drug product quality assurance.
- Lead training for qualification of visual inspection inspectors.
- Developing and maintaining defect library.
- Provide support to visual inspection inspectors in shop floor during batch manufacturing.
- Perform method suitability exercise (GMP risk assessment) of new products and train visual inspection inspectors on specifics.
- Lead investigation of visual inspection related deviations and OOX and implement CAPAs.
- Maintaining database and providing results related to visual inspection of manufactured drug product.
- Co-creating VI SOP landscape within NVS and implementation of SOP according to Clinical Drug Product Manufacturing requirements and specifics.
- Providing technical expertise during regulatory inspections and ensuring compliance with regulatory requirements.
- Proactive review and improvement of visual inspection strategies within Clinical Drug Product manufacturing.

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 experience in visual inspection/ particle characterization or other relevant experience; thorough knowledge of cGMP requirements

We offer **permanent employment** with **6 months** of probation period. Submit your application with the CV in English language.

Benefits and Rewards: 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 (Well-being), Unlimited learning and development opportunities.

Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally:

https://www.novartis.com/careers/benefits-rewards

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
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
Regul ä r

Shift Work
No

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Višji strokovnjak za področje vizualne kontrole (m/ž/d) / Senior Visual Inspection Expert (m/f/d)

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List of links present in page

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