Specialist MS&T /MS&T Technical Specialist-2

Job ID
REQ-10027112
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Eslovenia

Resumen

Kot Specialist MS&T boste izvajali in upravljali postopek validacije procesa in čiščenja, uvedbo in skladnosti opreme ter primarne embalaže in aktivnosti upravljanja sprememb, da bi zadostili zahtevam cGMP (Dobra proizvodna praksa) in nivojem kakovosti ter zagotovili, da so validacijski programi izvedeni skladno s postavljenimi časovnicami in z globalnimi regulatornimi pričakovanji.

English:

As MS&T Technical Specialist you will be executing and managing process validation, primary packaging, cleaning validation activities and change management activities to meet cGMP requirements on time and quality to ensure that site validation programs are compliant with global regulatory expectations.

About the Role

Vaše ključne odgovornosti:

- Podpora proizvodnim lokacijah pri vzdrževanju strategije nadzora nad procesi in ustrezno validacijo procesov
- Podpiranje aktivnosti življenjskega cikla procesne validacije tako, da zagotovite, da se stanje nadzora vzdržuje prek stalnega preverjanja procesa (OPV).
- Upravljanje transferjev izdelkov in uvajanje novih izdelkov v proces proizvodnje-
- Upoštevanje ustreznih predpisov GxP, SOP, HSE in drugih novartisovih smernic dobre dokumentacijske in proizvodne prakse
- Iskanje možnosti izboljšav obstoječih procesov, predlaganje poslovnih primerov.
- Sodelovanje pri pripravi in vzdrževanju proizvodnih navodil, planov, poročil, splošnih postopkov (SOP) in predlog.
- Podpiranje kvalifikacije in kalibracije proizvodne/pilotske opreme s spremljajočo dokumentacijo, načrtovanje in izvajanje rednega vzdrževanja.
- Načrtovanje, izvedba in dokumentacija proizvodnih poskusov (formulacijskih/validacijskih testov itd.) za dodeljene izdelke v kontekstu prenosa procesov, izboljšav procesov in procesne validacije.

Vaš doprinos k delovnem mestu:

- Univerzitetna stopnja izobrazbe iz farmacevtske tehnologije, kemije, farmacije, inženiringa ali druge ustrezne znanstvene smeri. Zaželen magisterij ali ustrezne izkušnje.
- Zaželeno poznavanje in izkušnje iz farmacevtske proizvodnje, GMP.
- Aktivno znanje angleškega jezika. Zaželeno znanje slovenskega jezika.

- Izkušnje s projektnim delom.
- Seznjanenost z Root Cause Analysis (Rca) in kontrolo procesa.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedoločen čas** s poskusno dobo **6 mesecev.**

Zakaj Novartis?

Naš namen je soustvarjati medicino za izboljšanje in podaljševanje življenja ljudi, naša vizija pa je postati najbolj cenjeno in zaupanja vredno farmacevtsko podjetje na svetu. Kako lahko to dosežemo? S pomočjo naših ljudi. Prav naši sodelavci nas vsak dan spodbujajo, da dosežemo svoje ambicije. Postanite del te misije in se nam pridružite! Več na spodnji povezavi: https://www.novartis.com/about/strategy/people-and-culture

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.

Pridružite se naši mreži Novartis:

V kolikor se ne prepoznate v zgornjem opisu delovnega mesta, vas vabimo, da se vpišete na spodnji povezavi v Novartisovo bazo talentov saj lahko tako vašo vlogo upoštevamo za podobne pozicije v prihodnosti: https://talentnetwork.novartis.com/network

English version:

Your key responsibilities:

- Support Product Steward in maintaining the process control strategy.
- Support process validation lifecycle activities by ensuring a state of control is maintained through ongoing process verification (OPV).
- Ensure that appropriate variables are identified for on-going monitoring as a contributor to quality risk management activities.
- Scientist MS&T -Comply with applicable GxP regulations, SOPs, HSE, ISEC And other Novartis Guidelines in the laboratory and, -Maintain up-to-date documentation of laboratory work carried out including documentation storage and archiving.
- Identify improvement options of current processes, propose business cases.
- Contribute to and maintain lab instructions, SOPs, templates.
- Support, qualification and calibration of lab / pilot equipment with accompanying documentation, schedule and perform routine maintenance.
- Design, execute and document experiments (formulation / analytical tests etc.) for products assigned in the context of process transfer, process improvement and process validation.

What you will bring to the role:

- University degree in pharmaceutical technology, chemistry, pharmacy, engineering, or other relevant scientific field.

Master's degree or relevant experience is desirable.
- Desirable knowledge and experience in pharmaceutical production, GMP.
- Fluent knowledge of English. Knowledge of Slovene language is desirable.
- Proficiency in MS Office tools.
- Excellent communication skills, ability to work independently, make decisions, and prioritize tasks.
- Experience in working on projects.
- Well versed in Root Cause Analysis (Rca) and Process Control.

We offer **permanent employment with 6 months of probation period**.

Commitment to Diversity & Inclusion:

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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.

Join our Novartis Network:

If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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

División

Operations
Business Unit
Innovative Medicines
Ubicación
Eslovenia
Sitio
Ljubljana
Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.
Alternative Location 1
Slovenj Gradec, Eslovenia
Functional Area
Technical Operations
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.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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