Specialist MS&T (ž /m/d)/MS&T Specialist (f/m/d)

Job ID
REQ-10043564

3月 07, 2025

Slovenia

摘要

Kot Specialist MS&T (Proizvodna znanost in tehnologija) boste v veliki meri odgovorni za osnovne MS&T aktivnosti kot so izvedba in nadzor procesne /pakirne validacije ter validacije č i š č enja, nadzor nad uvedbo sprememb, aktivnosti v povezavi z vpeljavo novih materialov, izvedba ocene tveganj na razli č nih podro č jih, itd. v sodelovanju z oddelki na razli č nih lokacijah v skladnu z njihovimi č asovnicami, potrebami in cilji.

As MS&T specialist you will be responsible for core Manufacturing Science and Technology activities such as Executing and managing process/primary packaging/ cleaning validation activities, Change management activities, Material implementation activities, Risk assessments etc. in collaboration with site team and according to site timelines, requirements and strategies and objectives.

About the Role

Va š e klju č ne odgovornosti:

- Strokovnjak za validacijo procesov in vzdr ž evanje procesov znotraj kontrolne strategije.
- Pretvoriti ustrezne parametre procesa in strategijo nadzora procesa v osredoto č en na č rt za validacijo procesa.
- Zagotavljanje tehni č nega znanja za vzpostavljanje in izvedbo ocene tveganj na kakovost izdelkov.
- Podpora validacijskim aktivnostim na lokacijah s pripravo glavnega na č rta validacije, dokumentov vezanih na procesno in pakirno validacijo ter validacijo č i š č enja in ponavljajo č o verifikacijo ustreznosti procesov.
- Podpora pri pisanju navodil za proizvodnjo, splo š nih postopkov za delo in obrazcev.
- Podpora pri oceni in implementaciji nove opreme in materialov.
- Priprava, izvedba in ustrezno dokumentiranje proizvodnih in laboratorijskih testov za produkte v fazi tehnolo š kega prenosa, sprememb in v procesu validacije.
- Priprava in pregled proizvodne (GxP) dokumentacije vklju č no z zahtevki za spremembe.
- Identificiranje mo ž nosti izbolj š av za procese in priprava na č rtov za uvedbo.

Va š doprinos k delovnem mestu:

- Dodiplomski š tudij farmacije, farmacevtske tehnologije, kemijskega in ž enirstva, biomedicinskega in ž enirstva, biotehnologije, kemije ali enakovrednih znanstvenih smeri. Za ž elen magisterij znanosti ali enakovredne izku š nje.
- Za ž elene izku š nje na podro č ju MS&T (Manufacturing Science & Technology), zagotavljanja kakovosti, regulacije ali pri proizvodnji farmacevtskih u č inkovin ali zdravil v farmacevtski proizvodnji.
- Dobro poznavanje ravnanja proizvodnje dokumentacije (validacijski poro č il, analiz rizika, primerjevalnih poro č il)
- Poznavanje programov za obvladovanje proizvodnje in ocenjevanje in obvladovanje tveganj.
- Teko č e znanje angle š č ine in sloven š č ine (ustno in pisno).

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

Zakaj Novartis?
Na š namen je soustvarjati medicino za izbolj š anje in podalj š evanje ž ivljenja ljudi, na š a vizija pa je postati najbolj cenjeno in zaupanja vredno farmacevtsko podjetje na svetu. Kako lahko to dose ž emo? S pomo č jo na š ih ljudi. Prav na š i sodelavci nas vsak dan spodbujajo, da dose ž emo svoje ambicije. Postanite del te misije in se nam pridru ž ite! Ve č na spodnji povezavi:
https://www.novartis.com/about/strategy/people-and-culture

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 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.

Pridru ž **ite se na** š **i mre** ž **i Novartis** Č e kolikor se ne prepoznate v zgornjem opisu delovnega mesta, vas vabimo, da se vpi š ete na spodnji povezavi v Novartisovo bazo talentov saj lahko tako va š o vlogo upo š tevamo za podobne pozicije v prihodnosti https://talentnetwork.novartis.com/network

English version:

Your key responsibilities:

- Support Product Steward in maintaining the process control strategy.
- Translate applicable process parameters and the process control strategy into a focused validation plan for process validation.
- Provide technical expertise and facilitate establishment of Quality Risk Assessment (as needed).
- Support site validation planning by writing and maintaining master plans for processes, cleaning, packaging processes and ongoing verification for processes and cleaning (as applicable).
- Support process validation lifecycle activities by ensuring a state of control is maintained through ongoing process verification (OPV).
- Contribute to and maintain production instructions, SOPs, templates.
- Contribute to the evaluation of new equipment and materials.
- Design, execute and document experiments (formulation / analytical tests etc.) for products assigned in the context of process transfer, process improvement and process validation.
- Prepare and review appropriate GxP documentation including change requests.
- Identify improvement options of current processes, propose business cases.

What you will bring to the role:

- Bachelor's degree in Pharmacy, Pharmaceutical Technology, Chemical Engineering, Biomedical engineering, Biotechnology, Chemistry, or equivalent. Desirable MSc/MS. or equivalent experience.
- Desired experience in Manufacturing Science & Technology (MS&T), Quality Assurance,

Regulatory or in the manufacturing of pharmaceuticals.
- Proficient knowledge on production related documentation (Validation reports, Risk analysis, Comparability reports).
- Familiar with risk assessment and risk management programs.
- Fluent in English and Slovene (oral and written).

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

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

部门
Operations

Business Unit
Innovative Medicines

地点
Slovenia

站点
Ljubljana

Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Alternative Location 1
Slovenj Gradec, Slovenia

Functional Area
Technical Operations

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.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.

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

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