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

Job ID
REQ-10017116
Aug 23, 2024
Slovenia

Summary

Kot Specialist MS&T (Proizvodna znanost in tehnologija) boste v veliki meri odgovorni za preiskovanje odstopanj kakovosti v sodelovanju s tehnologi proizvodnih procesov in večnamenskimi operativnimi skupinami na lokaciji. Imeli boste ključno vlogo pri omogočanju učinkovite komunikacije med skupinami in podpiranju dejavnosti reševanja težav ter prispevali k izboljšanju kakovosti, produktivnosti in učinkovitosti s podpiranjem in spodbujanjem izboljšav v organizaciji.

English:

As MS&T (Manufacturing Science and Technology) Technical Specialist you will be responsible for investigation of site quality deviations collaboratively with process experts and the multifunctional operations teams and take ownership of the deviation management for the site. You will play a key role in facilitating effective communication between teams and supporting problem-solving activities and contribute to the enhancement of quality, productivity, and efficiency by supporting and driving improvements within the organization.

About the Role

Ključne odgovornosti:

- Zagotavljanje tehničnega strokovnega znanja in vzpostavitev ocene tveganja za kakovost.

- Pretvoriti ustrezne parametre procesa in strategijo nadzora procesa v osredotočen načrt za validacijo procesa.

- Zagotavljanje opredelitve ustreznih spremenljivk, ki vplivajo na ustrezno kakovost aktivnosti.

- Podpora načrtovanja validacije s pisanjem in vzdrževanjem načrtov za procese, čiščenje, postopke pakiranja ter preverjanje procesov in čiščenja.

- Podpora zagotavljanja stabilnega procesa in ohranjanja nadzora s stalnim preverjanjem procesov (ongoing process verification).

- Prispevanje k laboratorijskim navodilom, SOP in predlogam ter vzdrževanje le-teh.

- Podpora, kvalifikacija in umerjanje laboratorijske/pilotne opreme s spremljajočo dokumentacijo, načrtovanje in izvajanje rednega vzdrževanja.

- Ugotavljanje možnosti za izboljšanje trenutnih procesov, predlaganje poslovnih primerov.

Vaš doprinos k delovnem mestu:

- Dodiplomski študij farmacije, farmacevtske tehnologije, kemijskega inženirstva, biomedicinskega inženirstva, biotehnologije, kemije ali enakovrednih znanstvenih smeri. Zaželen magisterij znanosti ali enakovredne izkušnje.

- Zaželene izkušnje na področju MS&T (Manufacturing Science & Technology), zagotavljanja kakovosti, regulacije ali pri proizvodnji farmacevtskih učinkovin ali zdravil v sterili/velikih molekulah.

- Dobro poznavanje ravnanja z odstopi, preiskavami incidentov, analize temeljnih vzrokov in upravljanja CAPA.

- Poznavanje programov za ocenjevanje in obvladovanje tveganj.

- Tekoče znanje angleščine (ustno in pisno).

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:

Key Responsibilities:

- Provide technical expertise and facilitate establishment of Quality Risk Assessment.
- Translate applicable process parameters and the process control strategy into a focused validation plan for process validation.
- Ensure that appropriate variables are identified for on-going monitoring as a contributor to quality risk management activities.

- Support site validation planning by writing and maintaining master plans for processes, cleaning, packaging processes and ongoing verification for processes and cleaning.
- Support process validation lifecycle activities by ensuring a state of control is maintained through ongoing process verification (OPV).
- Contribute to and maintain lab instructions, SOPs, templates.
- Support, qualification and calibration of lab/pilot equipment with accompanying documentation, schedule and perform routine maintenance.
- Identify improvement options of current processes, propose business cases.

What you'll bring to the role:

- Bachelor's degree in pharmacy, Pharmaceutical Technology, Chemical Engineering, Biomedical engineering, Biotechnology, Chemistry, or equivalent science streams. Desirable MSc/MS. or equivalent experience.
- Desired experience in MS&T, Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substance or drug products in Sterile/Large Molecules platform/facility.
- Proficient knowledge on deviation handling, incident investigations, root cause analysis, and CAPA management.
- Familiar with risk assessment and risk management programs.
- Fluent in English (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 morehere: 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

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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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Business Unit
Innovative Medicines
Location
Slovenia
Site
Ljubljana
Company / Legal Entity
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Alternative Location 1
Slovenj Gradec, Slovenia
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No
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