Ekspert tehnologije izdelkov I (m/ž/d) / Product Steward I (m/f/d)

Job ID
REQ-10045294
Apr 01, 2025
Slovenia

Summary

Kot Ekspert tehnologije izdelkov I boste odgovorni za vsebinsko poznavanje izdelkov skozi življenjski cikel. Pri tem je odgovoren za ohranjanje zmogljivosti procesov, vrednotenih s pomočjo statističnih analiz kritičnih parametrov. Skrbi za to, da so procesi robustni, v stalnem stanju validiranosti in neprestanih izboljšav.
Skrbi za prenos znanja in informacij med funkcijami ter lokacijami ter nudi strokovno podporo proizvodnji, skladno z zakonodajo, internimi predpisi, dobrimi praksami in poslovnimi cilji.

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We are seeking a Product Steward I. In this role, you will own the process knowledge of the product(s) assigned throughout the commercial lifecycle, maintains the oversight on process capability, through data trending and statistical analysis of critical variables, ensuring process(es) are robust, in continued state of validation and continuously improving. Ensures seamless flow of knowledge and information across functions, and with other Sites when applicable, with focus on the assigned product(s). Provides second line technical/scientific process support, in accordance with legislation, internal rules, good practices and business objectives.

About the Role

Vaše ključne odgovornosti:

Poznavanje tehnologije in opreme:

- Ohranja nadzor nad celotnim proizvodnim procesom na lokaciji in v celotnem življenjskem ciklu komercializacije, od prenosa iz razvoja do tega trenutka, in vzdržuje ustrezno znanje.
- Pripravlja in vzdržuje analizo tveganja glede kakovosti za posamezne izdelke (QRA).
- S pomočjo statistične analize in rednim spremljanjem trendov podatkov za posamezne izdelke po potrebi spremlja vse kritične spremenljivke in ključne spremenljivke.
- Pregleduje APQR in sprejema odločitve glede stanja nadzora.
- Zagotavlja pripravljenost na inšpekcijske preglede za vse procesne vidike izdelkov, ki so mu dodeljeni.
- Sledi in ocenjuje uspešnost izdelka, trende, zaznava probleme, izvajanje CAPA.
- Vodi / podpira raziskavo temeljnih vzrokov za napake v procesih, sproža izvajanje projektov za izboljšave izdelkov in jih vodi, pri tem pa v sodelovanje vključi medfunkcijske ekipe.
- Pomaga pri pobudi za izvajanje spremljanja vseh kritičnih medfaznih kontrol za posamezne izdelke ter sprošča parametre v vsakem laboratoriju (prenos QRA za posamezne izdelke)
- Skrbi za vidnost podatkov in trendov ter za seznanjanje z njimi na nivoju proizvodnje.

- Predstavlja uspešnost izdelkov in status projektov za izboljšave izdelkov na odboru za pregled robustnosti proizvodnje (MRRB).

Vaš doprinos k delovnem mestu:

- Univerzitetna diploma iz farmacije, farmacevtske tehnologije, kemije ali druge ustrezne znanstvene smeri. Zaželen magisterij iz omenjenih smeri.
- Aktivno znanje angleškega jezika
- Poznavanje orodja Microsoft Office
- Minimalno 5 let delovnih izkušenj pri podpori procesov na področju proizvodnje / proizvodne znanosti in tehnologije / tehničnega razvoja / kakovosti

Z izbranim kandidatom bomo sklenili delovno razmerje za **določen čas enega leta** s poskusno dobo **6 mesecev.** Prijavo oddajte z življenjepisom v slovenskem in angleškem jeziku.

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, 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.

V Novartisu si prizadevamo k vključenosti 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 pišite na naslov diversity.inclusion_slo@novartis.com in navedite, kakšne prilagoditve potrebujete ter vaše kontaktne podatke. Prosimo, vključite tudi podatek o številki razpisa, na katerega se prijavljate.

Your key responsibilities:

- Maintain the oversight and knowledge for entire manufacturing process performed on site and throughout the entire commercial lifecycle, since transfer from development to date, act as SPOC.
- Create and maintain a product specific Quality Risk Analysis (QRAs).
- Monitor all critical variables and key variables as appropriate using statistical analysis and conducting regular product specific data trending.
- Review APQR and decide on state of control.

- Ensure inspection readiness for all process related aspects of assigned products.
- Track and evaluate product performance, trending, detect issues, implementation of CAPAs.
- Lead / support root cause investigation of process failures, initiate and lead product improvement projects, involving cross-functional teams.
- Assist initiating the product-specific monitoring of all critical In Process Controls (IPC) and release parameters in each laboratory (transfer of the product-specific QRA).
- Ensure data and trending are visible and communicated at shop floor level.
- Present product performance and status of product improvement projects in site Manufacturing Robustness.

Essential Requirements:

- BSc. in Pharmacy, Pharmaceutical Technology, Chemistry or equivalent scientific degree. Desirable MSc. or equivalent experience.
- Functional knowledge of English.
- Knowledge of Microsoft Office.
- Minimum 5 years' experience in process support in manufacturing/ manufacturing science and technology/technical development/quality.

We offer **temporary employment** of one year 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 (Wellbeing), 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.

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.

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

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Business Unit
Innovative Medicines
Location
Slovenia
Site
Mengeš
Company / Legal Entity
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Functional Area
Technical Operations
Job Type
Full time
Employment Type
Temporary (Fixed Term)
Shift Work
No
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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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