

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

Job ID

REQ-10070340

Mar 05, 2026

LOC_SI

About the Role

Vaše ključne odgovornosti:

- Nadzira in vzdržuje znanje o izdelku in proizvodnem procesu skozi celotni življenjski cikel.
- Prispeva, ustvarja, pregleduje in vzdržuje dokumente za posamezne izdelke, npr. analizo tveganja kakovosti (QRA), kontrolno strategijo, validacijsko in kontinuirano verifikacijsko dokumentacijo (OPV), pregled kvalitete izdelka (APQR).
- Spremlja procese s statistično analizo in rednim spremljanjem trendov podatkov o posameznih izdelkih, ocenjuje učinkovitost procesov, zaznava težave in zagotavlja izvajanje korektivnih in preventivnih akcij.
- Zagotavlja pripravljenost za inšpekcijske preglede za vse procese, povezane z dodeljenim izdelkom.
- Sodeluje pri raziskavah vzrokov procesnih napak, sodeluje pri projektih za procesne izboljšave, ki vključujejo strokovnjake z različnih funkcij.
- Ocenjuje vpliv tehničnih sprememb na izdelek, procese, status validiranosti, registracijsko dokumentacijo, tehnično izvedljivost, vire in poslovno tveganje ter predlaga strategijo izvedbe.
- Sodeluje pri strategiji registracije in podpira registracijske dejavnosti.

Vaš doprinos k delovnem mestu:

- Univerzitetna stopnja izobrazbe iz farmacije, farmacevtske tehnologije, biotehnologije, kemije, inženirskih znanosti ali druge ustrezne znanstvene smeri. Zaželen magisterij.
- Najmanj 5 let delovnih izkušenj iz farmacevtske proizvodnje, proizvodnje bioloških učinkovin ali primerljivih izkušenj (npr. prehrabena, druga GMP regulirana proizvodnja).
- Aktivno znanje angleškega jezika.
- Dokazano obvladovanje pisanja in pregledovanje tehnične dokumentacije.
- Dobre komunikacijske sposobnosti, proaktivnost, samoiniciativnost, strokovnost, ciljna naravnost.
- Dobro upravljanje z različnimi deležniki.
- Zmožnost delovanja v globalnem okolju.

Zaželene izkušnje:

- Izkušnje iz projektnega vodenja v več-funkcijskem okolju.
- Uporaba statističnih orodij.

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

Ugodnosti in nagrajevanje:

Konkurenčen plačni paket, letni bonus, fleksibilen način dela z možnostjo prilagajanja urnika in delom od doma, pokojninska shema, shema nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju telesnega, duševnega in fizičnega počutja (iniciativa Polni življenja), številne priložnosti za učenje in razvoj.

Preberite naš priročnik, da spoznate načine, s katerimi bomo spodbujali vaš osebni in profesionalni razvoj:

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

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 Novartis: Ni pravo delovno mesto za vas? Prijavite se v našo bazo talentov, da ostanete v kontaktu z nami in se seznanite z ustreznimi kariernimi priložnostmi takoj, ko se pojavijo: <https://talentnetwork.novartis.com/network>

English version:

Key Responsibilities:

- Maintains the oversight and knowledge for entire manufacturing process performed on site and throughout the entire commercial lifecycle, since transfer from development to date, including life cycle management activities.
- Contributes, creates, reviews and maintains a product specific documents, e.g. Quality Risk Analysis (QRAs), control strategy, validation and ongoing process verification (OPV) documentation, and APQR.
- Monitors processes using statistical analysis and conducting regular product specific data trending, evaluates process performance, detects issues, and ensures implementation of CAPAs.
- Ensures inspection readiness for all process related aspects of assigned products.
- Leads / supports root cause investigation of process failures, initiates and leads product improvement projects, involving cross-functional teams.
- Assess impact of technical changes on product, process, process validation status, registration documentation, technical feasibility, resources and business risk and propose implementation strategy.
- Contributes to registration strategy and supports registration activities.

What you will bring to the role:

- BSc. in Chemistry, Pharmacy, Biotechnology, Pharmaceutical Technology or other science degree. Desirable MsC.
- Minimum 5 years experience in pharmaceutical manufacturing, GMP manufacturing, technical development, quality or comparable highly regulated industry.
- Proven understanding of quality systems and regulatory requirements across multiple health authorities.
- Expert in reviewing and writing technical reports.
- Proven project management experience in a cross-functional environment
- Functional knowledge of English.
- Effective stakeholder management.
- Ability to operate in a global environment.

Desired experience:

- Project management experience in a cross-functional environment.
- Experience with the use of statistical tools.

We offer permanent employment with 6 months of probation period.

Benefits and Rewards:

Competitive salary, Annual bonus, Flexible working schedule, tailored to your needs, possibility to work from home, Pension scheme, possibility of joining collective health insurance scheme, Employee Recognition Scheme, Expanded program for the promotion of health in the field of physical and mental well-being and managing workload (Well-being), 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>

Role Requirements

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>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.

[Read our handbook \(PDF 30 MB\)](#)

Division

DIV_TO

Business Unit

Development

Location

LOC_SI

Site

Mengeš

Company / Legal Entity

SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Functional Area

FCT_TO

Job Type

Full time

Employment Type

Regular

Shift Work

No

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