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

Job ID
391324BR
Mai 10, 2024
Slowenien

Zusammenfassung

Iščemo visoko motiviranega sodelavca, ki se bo pridružil naši MS&T ekipi pri širjenju proizvodnih zmogljivosti za proizvodnjo bioloških zdravil. Edinstven pristop k “single-use” tehnologiji nam omogoča proizvodnjo visokokakovostnih bioloških zdravil z neprimerljivo učinkovitostjo. Z našo najsodobnejšo tehnologijo in procesi, širokim naborom bioloških zdravil ter našim znanjem, predanostjo in vrhunskimi ekipami sodelavcev smo tovarna prihodnosti in z veseljem pozdravljamo talentiranega posameznika v naši ekipi.

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We are seeking a highly motivated product steward to join MS&T team as we expand our manufacturing capabilities for the production of biologics. Our unique approach to single-use technology allows us to produce high-quality biological drugs substances with unparalleled efficiency. Our state-of-the-art technology and processes, a wide range of biological molecules, engaged and highly motivated teams committed to improve people’s lives make us a factory of the future, and we are eager to welcome a talented individual to our team.

About the Role

Kot **Ekspert tehnologije izdelkov I** ste lastnik znanja za dodeljene izdelke in procese. Odgovorni boste za spremljanje proizvodnih procesov dodeljenih izdelkov skozi njihov celotni življenjski cikel od prenosa tehnologije, lansiranja in komercialne faze, vključno s karakterizacijo procesov in projekti življenjskega cikla. Z rednim spremljanjem in statistično analizo procesnih podatkov spremljate stabilnost in robustnost procesov, ter omogočate procesne izboljšave. Pravočasno in z razpoložljivimi viri boste pripravili, upravljali in izvajali dejavnosti, povezane z življenjskim ciklom izdelka, v skladu s cGMP, internimi standardi in poslovnimi cilji.

Idealen kandidat za to delovno mesto je ciljno usmerjen, ima močno analitično miselnost in naravnanost h kvaliteti, odlične komunikacijske sposobnosti, učinkovito sodeluje v timih in ima željo po nenehnem izboljševanju in rasti. Če imate ustrezna znanja in lastnosti, ste navdušeni nad proizvodnjo bioloških zdravil in bi želeli postati del naše ekipe, vam svetujemo, da se prijavite še danes.

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 kontinuirana 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.
• Podpira in vodi raziskave vzrokov procesnih napak, sproži in vodi projekte za izboljšanje procesov, 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 ali doktorat.
• Vsaj 5 let delovnih izkušenj iz farmacevtske proizvodnje, proizvodnje bioloških učinkovin, ali 8 let primerljivih izkušenj (npr. živilska, druga GMP regulirana proizvodnja).
• Aktivno znanje angleškega jezika.
• Poznavanje sistemov kakovosti in regulatornih zahtev
• Dokazano obvladovanje pisanja in pregledovanje tehnične dokumentacije
• Dobre komunikacijske sposobnosti, proaktivnost, samoiniciativnost, strokovnost, ciljna naravnanost.

Zaželene izkušnje:
• Izkušnje iz projektnega vodenja v več-funkcijskem okolju.
• Uporaba statističnih orodij.
• Dobro upravljanje z različnimi deležniki.
• Zmožnost delovanja v globalnem okolju.

Z izbranim kandidatom bomo sklenili delovno razmerje za **določen čas enega leta** 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

Location: Mengeš #LI-Hybrid

As a **Product Steward I (m/f/d)** you own the process knowledge of the product(s) assigned throughout the lifecycle, supporting manufacturing process transfers and GMP production. With oversight on process capability, through data trending and statistical analysis you will ensure that our manufacturing process(es) are robust, in continued state of validation and continuously improving. You will prepare, manage and execute product lifecycle related activities on time and with available resources, in accordance with cGMP, internal standards, and business goals.

The ideal candidate for this position will possess a strong analytical and quality mindset, broad knowledge of biopharmaceuticals, and drive for constant improvement and growth. If you are passionate about biopharmaceuticals, striving for improvement of people's lives and interested in being a part of a team that is leading the way in the industry, we encourage you to apply today.

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.
• Assesses the impact of technical changes on product, process, process validation status, registration documentation, technical feasibility, resources and business risk and proposes implementation strategy.
• Contributes to registration strategy and supports registration activities.

Essential Requirements:
• BSc. in Chemistry, Pharmacy, Biotechnology, Pharmaceutical Technology or other science degree. Desirable MsC / PhD in the above or equivalent.
• Minimum 5 years experience in pharmaceutical manufacturing, GMP manufacturing, technical development or quality or 8 years in comparable highly regulated industry.
• Functional knowledge of English.
• Proven understanding of quality systems and regulatory requirements across multiple health authorities.
• Expert in reviewing and writing technical reports.
• Good communication skills, proactive behaviour, result-driven.

Desirable Requirements:
• Proven project management experience in a cross-functional environment.
• Knowledge of statistical tools.
• Good management with different stakeholders.
• Ability to operate in a global environment.

We offer a **temporary 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 (Wellbeing), employment at Top SI Employer, 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

Abteilung
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Business Unit
Innovative Medicines
Ort
Slowenien
Website
Mengeš
Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Temporary (Fixed Term)

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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