Vi š ji Ekspert upravljanja kakovosti - skladnost (m/ ž /d) / Senior Regulatory CMC facilitator (m/f/d)

Job ID
REQ-10055464

7月 03, 2025

Slovenia

摘要

#LI-Hybrid

Ste pripravljeni na karierno prilo ž nost, kjer bo va š prispevek klju č en za uvajanje inovativnih zdravil na trg? Na na š em oddelku za kakovost - skladnost, male molekule, i š č emo strokovnjaka za upravljanje kakovosti, ki bo s svojim znanjem in izku š njami usklajeval regulativne dejavnosti CMC, povezane z lansiranjem ter aktivnostmi po odobritvi zdravil.

Č e vas navdu š uje delo, ki vpliva na pravo č asno dostopnost naprednih terapij in zagotavljanje najvi š jih standardov kakovosti, vas vabimo, da se nam pridru ž ite in pustite svoj pe č at!

Are you ready for a career opportunity where your contributions will play a key role in bringing innovative medicines to market? Our Quality - Compliance, Small Molecules department is looking for a Quality Management Specialist to coordinate and manage CMC regulatory activities related to

product launches and post-approval processes.

If you're passionate about ensuring timely access to advanced therapies while maintaining the highest quality standards, we invite you to join us and make your mark

About the Role

Vaše ključne odgovornosti:

- Osrednja kontaktna oseba in svetovalec za svetovno regulativno obveščenost na lokaciji. Tesno sodelovanje z Global Reg CMC, spremljanje novih regulativnih zahtev, strategij Global Reg CMC in poznavanje globalnih produktnih dosjejev (CTD modul 3).
- Izvajanje neodvisnih predhodnih ocen novih zahtevkov za spremembe. Upoštevanje trenutnih regulativnih zahtev in trendov, zagotavljanje natančnosti in popolnosti regulativno pomembnih informacij v zahtevkih za spremembe ter vključevanje morebitnih regulativnih ovir. Sledenje tematskim regulativnim vprašanjem za specifične produkte po konsolidaciji vseh informacij, na voljo na lokaciji.
- Podpora lokaciji pri pripravi učinkovitih strategij za nadzor sprememb, predvsem sprememb, ki vplivajo na širok spekter produktov ali drugih lokacij/divizij.
- Podpora pri pripravi dokumentacije za variacije s pomočjo pravočasnega zagotavljanja kakovostne izvorne dokumentacije in natančnih pripomb strokovnjakov s področja tehnike za Global Reg CMC, ob zagotavljanju regulativne skladnosti.
- Omogočanje pravočasnega pisanja visokokakovostnih CMC modulov na lokaciji v skladu z dogovorjenimi regulativnimi strategijami CMC, zagotavljanje tehničnega in regulativne skladnosti ter spodbujanje najboljših praks (npr. LEAN).
- Podpora pri pripravi odgovorov CMC na vprašanja zdravstvenih organov glede specifičnih produktov na lokaciji.
- Pregled obveznosti, ki vplivajo na lokacijo. Usposabljanje in razvoj osebja lokacije glede regulativnih specifičnih vidikov upravljanja sprememb z deljenjem naukov in informacij o regulativni obveščenosti z namenom izboljšanja njihovih veščin in sposobnosti pri obvladovanju zahtevkov za spremembe ter ohranjanja najvišje stopnje skladnosti.

Vaš doprinos k delovnem mestu:

- Visoka šolska stopnja izobrazbe farmacevtske, biološke, kemijske, mikrobiološke ali druge ustrezne naravoslovne smeri.
- Aktivno znanje angleškega jezika.
- Minimalno 5 let izkušenj na področju regulative (modul 3) in vsaj 10 let delovnih izkušenj iz GMP področja (proizvodnja, kakovost).
- Poznavanje lokalnih in globalnih predpisov ter postopkov predložitve in odobritve novih kemisjkih molekul in upravljanje življenjskega cikla izdelkov.
- Odličnе pogajalske in komunikacijske sposobnosti ter strateško razmišljanje.
- Odličnе organizacijske sposobnosti. Proaktiven in akcijsko usmerjen odnos pri vodenju projektov.
- Poznavanje orodja Microsoft Office, MS-Project, sistemov za upravljanje dokumentov, baz podatkov in sposobnost hitrega učenja nove programske opreme, orodij za sledenje in

povezanih procesov.

Z izbranim kandidatom bomo sklenili delovno razmerje za nedolo č en č as s poskusno dobo 6 mesecev. Prijavo oddajte z ž ivljenjepisom v slovenskem in angle š kem jeziku.

Ugodnosti in nagrajevanje: Konkuren č en pla č ni paket, letni bonus, fleksibilen na č in dela z mo ž nostjo prilagajanja urnika in delom od doma, pokojninska shema, shema nagrajevanja in priznanja dose ž kov, raz š irjeni program promocije zdravja na podro č ju telesnega, du š evnega in fizi č nega po č utja (iniciativa Polni ž ivljenja), š tevilne prilo ž nosti za u č enje in razvoj.

Preberite na š priro č nik, da spoznate na č ine, s katerimi bomo spodbujali va š osebni in profesionalni razvoj: https://www.novartis.com/careers/benefits-rewards

Zakaj Novartis: Pomagati bolnikom in njihovim dru ž inam zahteva ve č kot le inovativno znanost. Potrebna je skupnost zavzetih ljudi, kot ste vi. V Novartisu cenimo sodelovanje, podporo in navdihovanje drug drugega za razvoj prebojnih terapij, ki spreminjajo ž ivljenja

pacientov. Ste pripravljeni ustvariti svetlej š o prihodnost skupaj z nami?
https://www.novartis.com/about/strategy/people-and-culture

Pridru ž ite se Novartisu: Ni pravo delovno mesto za vas? Prijavite se v na š o bazo talentov, da ostanete v kontaktu z nami in se seznanite z ustreznimi kariernimi prilo ž nostmi takoj, ko se pojavijo: https://talentnetwork.novartis.com/network

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.

Dostop in prilagoditve: V Novartisu si prizadevamo k vklju č enosti 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 pi š ite na naslov diversity.inclusionslo@novartis.com in navedite, kak š ne prilagoditve potrebujete ter va š e kontaktne podatke. Prosimo, vklju č ite tudi podatek o š tevilki razpisa, na katerega se prijavljate.

Key Responsibilities:

- Act as single point of contact and advisor for worldwide regulatory information on the site. Maintain a close collaboration with Global Reg CMC in order to keep track with new regulatory requirements, Global Reg CMC strategies and the knowledge of the global product

dossiers (CTD module 3).
- Perform the product independent pre-evaluation of new change requests. Consider current regulatory requirements and trends in order to ensure accuracy and completeness of regulatory relevant information in the change requests while including potential regulatory challanges. Follow up with Reg CMC for product specific regulatory topics after having consolidated all information available at the site.
- Support the site in generation of effective change control strategies particularly when changes affect a wide range of products or other sites/divisions.
- Support the variation documentation preparation by facilitating timely provision of good quality source documentation and accurate comments from technical experts to Global Reg CMC while ensuring regulatory compliance.
- Facilitate the timely writing of high-quality CMC modules on site in line with agreed CMC regulatory strategies, assuring technical congruency, regulatory compliance and adherence to best practices (e.g. LEAN).
- Support the preparation of CMC responses to health authority questions for site specific products.
- Maintain overview on commitments impacting the site. Train and develop the site ' s personnel on regulatory specific aspects of change management by sharing lessons learned and regulatory intelligence information with the goal of improving their skills and capabilities for handling change requests and keeping the highest level of compliance.

Essential Requirements:

- Degree in Science (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent.
- Fluent English (oral & written).
- At least 5 years of experience in the regulatory field (module 3) and at least 10 years of work experience in the GMP field (production, quality). Working Knowledge of local and global regulations and submission and approval processes for New Chemical Molecules and product life cycle management.
- Excellence in negotiation and communication skills as well as capability to influence others in a matrix organization with the necessary strategic thinking.
- Excellent organizational skills. Proactive and action-oriented attitude in driving projects.
- Computer literacy in MS-project, Power Point, document management systems, databases and ability to quickly learn new software, tracking tools and associated processes.

We offer permanent employment with 6 months of probation period. Submit your application with the CV in Slovenian and English language.

Benefits and Rewards: 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 (Well-being), Unlimited learning and development opportunities.

Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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

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.

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.

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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
Menge š

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

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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