Ekspert upravljanja kakovosti – skladnost (m/ž/d) / Regulatory CMC facilitator (m/f/d), Mengeš

Job ID
REQ-10037816
Feb 04, 2025
Slovenia

Summary

Iščemo Eksperta upravljanja kakovosti – skladnost.

Vas zanima upravljanje in usklajevanje regulativnih dejavnosti CMC, povezanih z lansiranjem in dejavnostmi po odobritvi inovativnih zdravil? Želite prispevati k pravočasni oskrbi trga, ob hkratnem izpolnjevanju vseh regulativnih zahtev?

_____

We are seeking a QA Compliance Expert.

Interested in managing and facilitating regulatory CMC related launch and post-approval activities of innovative medicines? Willing to contribute timely market supply while complying with regulatory obligations?

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, dodeljevanje/potrjevanje klasifikacije v kategoriji I ali II. 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 tehnične in regulativne skladnosti ter spoštovanje 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:

- Visokošolska stopnja izobrazbe farmacevtske, biološke, kemijske, mikrobiološke ali druge ustrezne naravoslovne smeri.
- Aktivno znanje angleškega jezika.
- Minimalno 2 leti delovnih izkušenj na področju proizvodnje, razvoja ali druge strokovne izkušnje na področju kakovosti.
- Poznavanje lokalnih in globalnih predpisov ter postopkov predložitve in odobritve novih kemičnih enot (NCE) in upravljanje življenjskega cikla izdelkov.
- Odlične pogajalske in komunikacijske sposobnosti ter strateško razmišljanje.
- Odlične 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 **nedoločen čas** s poskusno dobo **6 mesecev.** Prijavo oddajte z življenjepisom v slovenskem in angleškem jeziku.

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.

Major accountabilities:

- Act as single point of contact and advisor for worldwide regulatory intelligence 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 to assign/confirm category I or category II classification. 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 hurdles. 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.

Minimum Requirements:

- Degree in Science (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent.
- Fluent English (oral & written).
- 2 years or more experience in Regulatory CMC and/ or working on a manufacturing site (e.g. QA, QC or production) or laboratory or equivalent experience from external company or other line function preferable.
- Working Knowledge of local and global regulations and submission and approval processes for New Chemical Entities (NCE) 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 are offering a **permanent employment contract**, including a 6-month probation period. Submit your application with the CV in English language.

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.

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

Division
Operations
Business Unit
Innovative Medicines
Location
Slovenia
Site
Mengeš
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
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.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Job ID
REQ-10037816

Ekspert upravljanja kakovosti – skladnost (m/ž/d) / Regulatory CMC facilitator (m/f/d), Mengeš

Apply to Job

Source URL: *https://www.adacap.com/careers/career-search/job/details/req-10037816-ekspert-upravljanja-kakovosti-skladnost-mzd-regulatory-cmc-facilitator-mfd-menges*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Menge/Regulatory-CMC-facilitator--m-f-d---Menge_REQ-10037816-2
5. mailto:diversity.inclusion_slo@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Menge/Regulatory-CMC-facilitator--m-f-d---Menge_REQ-10037816-2