Ekspert upravljanja kakovosti ESO FDF I (m/ž/d) / QA Senior Manager ESO FDF (m/f/d)

Job ID
REQ-10029540
Nov 18, 2024
Slovenia

About the Role

Vaše ključne odgovornosti:

- Kontaktna oseba za vse aktivnosti pri zunanjih dobaviteljih, povezanih s kakovostjo.
- Odgovornost za izdelavo ocen tveganja zunanjih dobaviteljev.
- Skrb, da je na voljo veljavna pogodba o zagotavljanju kakovosti, skladna z zahtevami globalne predloge, ki jasno opredeljuje vloge in odgovornosti cGMP med Novartisom in zunanjim dobaviteljem, ter podrobne podatke in zahteve o izdelku.
- Obravnavanje kritičnih problemov glede kakovosti (odstope, reklamacije, odpoklice, ponaredbe in nedovoljeno poseganje v izdelke, neustrezni rezultati stabilnosti itd.) v skladu s pogodbo o kakovosti in Poslovnikom kakovosti v Novartisu. Skrbi za pravilno izvedbo raziskav.
- Sodelovanje pri pripravi predlogov za spremembe, bodisi zunanjega dobavitelja ali Novartisa, ter skrb za to, da se obravnavajo v skladu s pogodbo o kakovosti in splošnimi postopki Novartisa od prevzema do izvedbe in zaključka.
- Sodelujovanje z drugimi funkcijami v Novartisu, ki tudi obvladujejo zunanje dobavitelje, in sicer z nabavo, pravno službo, oskrbo, regulatornim CMC, registracijami zdravil, itd.
- Odgovornost za osebni in strokovni razvoj.
- Izvajanje in upoštevanje vseh navodil in zahtev za zagotavljanje varnega dela, varovanja okolja in premoženja.
- Ostale naloge določene z letnim pogovorom o ciljih in s kazalniki uspešnosti.
- Druge naloge po navodilu nadrejenega in naloge na podlagi posebnega imenovanja.

Vaš doprinos k delovnem mestu:

- Visokošolska izobrazba farmacevtske, kemijske ali druge primerne smeri.
- Tekoče znanje angleškega jezika.
- Poznavanje orodja MS Office.
- Pet let delovnih izkušenj s področja upravljanja kakovosti, kontrole kakovosti, proizvodnje, regulative ali drugega primernega strokovnega področja.

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

Prijave z življenjepisom lahko oddate preko spletne povezave.

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.

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

Key Responsibilities:

- Acts as Single Point of Contact / SPOC for all quality related activities at the External Supplier
- Responsible for producing risk assessments of external suppliers
- Ensure that a valid QA agreement defined in line with the requirements of the Global template is in place which clearly defines cGMP roles and responsibilities between Novartis and the External Supplier, as well as Product details and requirements.
- Manage critical quality issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc.) according to the Quality Agreement and the Novartis Quality Manual. Ensure investigations are correctly executed.
- Cooperate at the preparation of change requests, either from the External Supplier or from Novartis, and ensures they are managed according to the Quality Agreement and Novartis SOPs from receipt, through to the implementation and closure.
- Collaborates with other functions at Novartis that also control external suppliers, namely purchasing, legal, procurement, regulatory CMC, drug registrations, etc.
- Responsibility for personal and professional development.
- Providing conditions for and control of the implementation of HSE tasks and requirements in the unit.
- Other tasks determined during the annual objectives setting process and by KPIs.
- Other tasks as assigned by the supervisor, and tasks based on a specific appointment.
-

Essential Requirements:

- University degree in pharmaceutical, chemical or other appropriate sciences.
- Fluent in English
- Knowledge of Microsoft Office
- Five years of work experience in the field of quality management, quality control, production, regulation or another appropriate professional field

We offer a permanent employment with 6 month probation period .

You are kindly invited to submit your application.

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 (Energized for Life).

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

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
Ljubljana
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

Job ID
REQ-10029540

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