NOVARTIS

Ekspert kakovosti II v tehničnem razvoju bioloških zdravil (m/ž/d) / Quality Manager (m/f/d)

Job ID
REQ-10087733
Sep 23, 2026
LOC_SI

About the Role

Glavne odgovornosti:

- Podpora vzdrževanju regulativno zahtevanih dokumentov za inšpekcijske preglede zdravstvenih organov ter pomoč pri upravljanju inšpekcij zdravstvenih organov Podpirajte pripravo kakovostnih načrtov (in pregledajte druge načrte glede kakovosti in varnosti) za klinične programe
- Podpirati pobude za ohranjanje ali izboljšanje kakovosti, uspešnosti in skladnosti operativnih dejavnosti, vključno z upravljanjem tveganj, poročanjem zdravstvenih organov, IT sistemi
- Podprite pobude, osredotočene na izboljšanje kakovosti, procesov in skladnosti, vključno z prepoznavanjem priložnosti ter razvijajte strategije za izboljšanje kakovosti ob zagotavljanju skladnosti z regulativnimi zahtevami Zagotovite, da so informacije, pridobljene med pobudami za kakovost in skladnost ter rezultati revizij in ocenjevanja, ocenjeni, da se prepoznajo morebitne regulativne, skladnostne in QA potrebe po usposabljanju
- Pomagati pri prepoznavanju težav s kakovostjo ter pomagati pri preiskavah temeljnih vzrokov in podpirati razvoj načrtov korektivnih in preventivnih ukrepov (CAPA), vključno s spremljanjem statusa, da se zagotovi, da so težave rešene, dokončane in dokumentirane.
- Nuditi pomoč pri odpravljanju odstopanj, zagotoviti spremljanje in spremljanje povezanih korektivnih in preventivnih ukrepov.
- Upravljati in podpirati vidike kakovosti projektov in dejavnosti, vključno s tistimi, povezanimi s tretjimi osebami, analitskimi instrumenti, proizvodno opremo, načrti kakovosti, usposabljanjem, IT validacijami itd.
- Pregledujte in odobrite kakovostne rezultate za zagotovitev skladnosti (vključno s postopki, dokumentacijo, delom tretjih oseb, pogodbeniki, gradivom kliničnih preskušanj, komponentami, ocenami vrzeli)
- Prijavljanje tehničnih pritožb / neželenih dogodkov / posebnih primerov, povezanih z izdelki Novartis, v 24 urah po prejemu
- Distribucija marketinških vzorcev (kjer je to primerno)

Ključni kazalniki uspešnosti:

- Sistem kakovosti grozdov je vzpostavljen in se nenehno posodablja, po potrebi pa se tveganja proaktivno prepoznajo in učinkovito zmanjšujejo
- Število in resnost težav, ugotovljenih med notranjimi in zunanjimi revizijami.
- Dokazano/priznano vodja specifičnega GxP; zgodnje zunanje/industrijsko sodelovanje
- Zadostno finančno znanje (npr. upravljanje stroškov, napoved proračuna itd.)
- Vzor kulture, vrednot in vedenj podjetja Novartis

Koristi in nagrade

V Novartisu smo zavezani skupnemu preoblikovanju medicine – in nagrajevanju ljudi, ki jo uresničijo. Pričakovani letni osnovni plačni razpon za delovno mesto: € 32,060 do €59,540 Osnovna plača je določena glede na spolno nevtralne cilje, kot so relevantne veščine, kompetence in izkušnje v skladu s politiko plač Novartisa, ob vstopu v Novartis pa se redno pregleduje. Poleg osnovne plače ste morda upravičeni do bonusa na podlagi uspešnosti, odvisno od določenih parametrov uspešnosti. Nagrade članstva v naši ekipi segajo daleč preko osnovne plače in spodbud. Ponujamo tudi različne konkurenčne ugodnosti, ki vam pomagajo uspevati osebno in poklicno, kot so zavarovalni načrti, pokojninski načrti, viri za dobrobit in globalni programi priznanja. Poleg tega ponujamo, kjer je mogoče, prilagodljive in hibridne možnosti dela ter

najmanj 14 tednov plačanega starševskega dopusta.

Major Accountabilities:

- Support maintenance of the regulatory -required files for health authority inspections and assist with health authority inspection management
- Support generation of Quality Plans (and review other plans for quality/safety aspects) for clinical programs
- Support initiatives to maintain or improve quality performance and compliance of operational activities including risk management, health authority reporting, IT systems
- Support initiatives focused on quality, process and compliance improvement, including identification of opportunities and develop strategies aimed at improving quality while ensuring compliance with regulatory requirements
- Ensure information gained during quality and compliance initiatives, as well as audit and assessment results, are evaluated to identify any regulatory, compliance and QA training needs
- Aid in the identification of quality issues and assist with root cause investigations and support the development of corrective and preventative action plans (CAPA), including monitoring status to Ensure issues are addressed, completed and documented.
- Provide assistance in the remediation of deviations, Ensure follow up and monitoring of associated corrective and preventive actions.
- Manage and Support quality aspects of projects and activities, including those related to third parties, analytical instruments, manufacturing equipment, quality plans, training, IT validations, etc.
- Review and approve quality deliverables to ensure compliance (including procedures, records, third party work, contractors, clinical trial material, components, gap assessments)
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt
- Distribution of marketing samples (where applicable)

Key Performance Indicators:

- Clusters Quality System in place and continuously updated, as required risks proactively identified and effectively mitigated
- The number and severity issues identified during internal and external audits.
- Demonstrated/recognized leader of specific GxP; early external/industry engagement
- Sufficient financial knowledge (e.g., cost management, budget forecast, etc.)
- Role Model of Novartis culture, values & behaviours

Benefits & Rewards

At Novartis, we’re committed to reimagining medicine together - and rewarding the people who make it happen.

Expected Annual Base Salary Range for role: €32,060 to € 59,540

The base salary offered is determined based on gender-neutral objectives, such as relevant skills, competencies and experience in accordance with the Novartis pay setting policy and upon joining Novartis will be reviewed periodically.

In addition to your base salary, you may be eligible for a performance-based bonus depending on certain performance parameters.

The rewards of being part of our team go far beyond base pay and incentives. We also offer a variety of competitive benefits in kind to help you thrive personally and professionally, such as insurance plans, retirement plans, wellbeing resources and global recognition programs. In addition, we provide flexible and hybrid working options, where possible, and minimum 14 weeks paid parental leave.

Role Requirements

Primary location salary range
€32,060.00 - €59,540.00
Division

DIV_GD
Business Unit
Quality
Location
LOC_SI
Site
Mengeš
Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
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