

Senior QA Operations Expert; Qualified Person (m/f/d)

Job ID

REQ-10074153

Июн. 22, 2026

Австрия

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Сводка

#LI-Hybrid

Location: Schafftenau, Austria

The Qualified Person (QP / Sachkundige Person) is responsible for the final certification and release of medicinal products in accordance with § 7 of the Arzneimittelbetriebsordnung (AMBO 2009).

Based in Austria, you will ensure that every batch is manufactured and tested in full compliance with the Austrian Medicines Act (AMG), the Marketing Authorization, and current GMP requirements. With clear legal accountability, you will verify product quality and documentation to ensure no batch is released—whether for the Austrian market or for export—without confirmed compliance.

About the Role

Major Accountabilities

- ~ Nadzor nad operacijami kakovosti na celotnem mestu.
- ~ Dohodni nadzor QA.
- ~ Odhodni nadzor QA.
- ~ pregled in odobritev MBR.
- ~ Sprostitev izdelka.
- ~ QA za nadzor kakovosti ter AS in T.
- ~ Operativna odličnost QA.
- ~ Sprožite in vozite lokalni postopek najema.
- ~ Črta odgovornost in dnevni sprehod.
- ~ Vodilni OpEx projekti.
- ~ Preiskava deviacije, OOX, pritožbe.
- ~ Opredeliti in izvajati SKP.
- ~ Podpora projektom prenosa in študijam potrjevanja.
- ~ Sledite meritvi ekipe in zagotovite, da KQI /KPI izpolnjuje zahteve.
- ~ pregled in odobritev besedila in načrta.
- ~ Poročanje o incidentih hse in ukrepanje.
- ~ Nova oprema za uporabo Podpora (OQ, PQ).
- ~ Opredelite področja izboljšav v postopku in izdelkih.
- ~ Načrtovanje virov in zmogljivosti (ljudi in opreme) ter upravljanje delovne obremenitve.
- ~ Uspešnost in vodstvo Podpora specializirani ekipi.
- ~ Po potrebi zagotoviti razpoložljivost opreme, kemikalij in potrošnega sredstva.
- ~ pregled in revizija SOP.
- ~ Opravite lokalno usposabljanje in spremljajte stanje usposabljanja.
- ~ Poročanje o tehničnih pritožbah / neželenih dogodkih / scenarijih posebnih primerov, povezanih z Novartis izdelki v roku 24 ur po prejemu
- ~ Distribucija vzorcev trženja (kjer je primerno)

Key Performance Indicators

- ~Uspešna podpora projektom z dogovorjeno kakovostjo in dobavnimi roki, opravljeni notranji in zunanji pregledi
- ~Spoznajte kakovost in časovnice za vse projekte
- ~Delovati v skladu z GMP, etiko, zdravstveno varnostjo in okoljem (HSE) ter informacijsko varnostjo (ISEC)
- ~Število in resnost težav cGMP, ugotovljenih med notranjimi in zunanjimi revizijami
- ~Podatki ob koncu leta v okviru proračuna

Work Experience

- ~Pomembna pogajanja
- ~Vodenje ljudi
- ~Vodenje operacij in izvrševanje
- ~Sodelovanje prek meja
- ~Vodenje projektov

Skills

- ~Ocene uspešnosti zaposlenih
- ~Upravljanje s človeškimi viri
- ~Qa (zagotavljanje kakovosti)

- ~Postopki dobre proizvodne prakse
- ~Upravljanje revizije
- ~Sposobnosti odločanja
- ~Pripravljenost na inšpekcijske preglede
- ~Sprostitev izdelka
- ~Organizacijske sposobnosti
- ~Upravljanje in vodenje ljudi
- ~Komunikacijske spretnosti
- ~Odpravljanje dvoumnosti
- ~Samozavedanje
- ~Stalno učenje
- ~Tehnološko strokovno znanje

Language

Angleščina

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>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.

[Read our handbook \(PDF 30 MB\)](#)

Primary location salary range

€85,300.00 - €158,300.00

Дивизион

Operations

Business Unit

Quality

Место

Австрия

Сайт

Schaftenau

Company / Legal Entity

AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area

Quality

Job Type

Full time

Employment Type

Redni sodelavec

Shift Work

No

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