

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

Job ID
REQ-10074153

4月 22, 2026

Austria

摘要

#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 odli nost QA.
- Spro ž ite in vozite lokalni postopek najema.
- rta odgovornost in dnevni sprehod.
- Vodilni OpEx projekti.
- Preiskava deviacije, OOX, prito ž be.
- Opredeliti in izvajati SKP.
- Podpora projektom prenosa in š tudijam potrjevanja.
- Sledite meritvi ekipe in zagotovite, da KQI /KPI izpolnjuje zahteve.
- pregled in odobritev besedila in na rta.
- Poro anje o incidentih hse in ukrepanje.
- Nova oprema za uporabo Podpora (OQ, PQ).
- Opredelite podro ja izboljš av v postopku in izdelkih.
- Na rtovanje virov in zmogljivosti (ljudi in opreme) ter upravljanje delovne obremenitve.
- Uspe š nost in vodstvo Podpora specializirani ekipi.
- Po potrebi zagotoviti razpolo ž ljivost opreme, kemikalij in potro š nega sredstva.
- pregled in revizija SOP.
- Opravite lokalno usposabljanje in spremljajte stanje usposabljanja.
- Poro anje o tehni nih prito ž bah / ne ž elenih dogodkih / scenarijih posebnih primerov, povezanih z Novartis izdelki v roku 24 ur po prejemu
- Distribucija vzorcev tr ž enja (kjer je primerno)

Key Performance Indicators

- Uspe š na podpora projektom z dogovorjeno kakovostjo in dobavnimi roki, opravljeni notranji in zunanji pregledi
- Spoznajte kakovost in asovnice za vse projekte
- Delovati v skladu z GMP, etiko, zdravstveno varnostjo in okoljem (HSE) ter informacijsko varnostjo (ISEC)
- Število in resnost te ž av cGMP, ugotovljenih med notranjimi in zunanjimi revizijami
- Podatki ob koncu leta v okviru prora una

Work Experience

- Pomembna pogajanja
- Vodenje ljudi
- Vodenje operacij in izvr š evanje
- Sodelovanje prek meja
- Vodenje projektov

Skills

- ocene uspe š nosti zaposlenih
- Upravljanje s š love š kimi 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 \(PDF 30 MB\)](#)

部门
Operations

Business Unit
Quality

地点
Austria

站点
Schafftenau

Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area
Quality

Job Type
Full time

Employment Type
Redni sodelavec

Shift Work
No

```
var config = { targetId: "kalturaplayer6a149bd7b5618740849214", provider: { widgetId:
"10m7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause:
false, allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: {},
sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true,
showSpeedMenu: false }, css : "/modules/custom/arcticnckalturaaddon/css/kalturavideo.css",
components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback',
'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
KalturaPlayer.ui.components.Remove } ] } }; // Check and add plugins only if they exist if
(KalturaPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if
(KalturaPlayer.plugins["transcript"]) { config.plugins["playkit-js-transcript"] = { position: "right", //
Default: bottom;('left', 'right', 'top', 'bottom') to enable transcript. expandMode: "over", // Default:
alongside;('alongside', 'hidden', 'over') expandOnFirstPlay: false, showTime: true, downloadDisabled:
false, printDisabled: false, disable: true }; } if (KalturaPlayer.plugins["preventSeek"]) {
config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; }
config.plugins.floating = { disable: true }; if (KalturaPlayer.plugins["navigation"]) {
config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible:
false }; } if (KalturaPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; }
if (KalturaPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if
(KalturaPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if
(KalturaPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents =
[]; if (KalturaPlayer.plugins["googleAnalytics"]) { config.plugins.googleTagManager = {};
config.plugins.googleTagManager.customEventsTracking = {};
config.plugins.googleTagManager.containerId = 'GTM-57RJQ5';
config.plugins.googleTagManager.customEventsTracking.custom = [];
config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents:
false, playlistEvents: false, castEvents: false } }; }
```

```
try { var kalturaPlayer = KalturaPlayer.setup(config); // Add the player to the global array. if (typeof kalturaPlayerVideos !== 'undefined') { kalturaPlayerVideos.push(kalturaPlayer); } else { var kalturaPlayerVideos = []; kalturaPlayerVideos.push(kalturaPlayer); } // Load the Player for other media. kalturaPlayer.loadMedia({entryId: "1_dgfvmafo"}); } catch (e) { console.error(e.message) }
```

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1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf>
3. <https://novartis.wd3.myworkdayjobs.com/sl-SI/NovartisCareers/job/Schaftenau/Senior-QA-Operations-Expert--Qualified-Person--m-f-d-REQ-10074153-2>
4. <https://novartis.wd3.myworkdayjobs.com/sl-SI/NovartisCareers/job/Schaftenau/Senior-QA-Operations-Expert--Qualified-Person--m-f-d-REQ-10074153-2>