

## 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: "kalturaplayer69fb1c619627c321916322", 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>