

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

Job ID
REQ-10074153

4月 15, 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

- Toezicht op kwaliteitsoperaties op de hele locatie.
- Inkomend QA-toezicht.
- Uitgaand QA Oversight.
- MBR-beoordeling en goedkeuring.
- Productrelease.
- QA voor Kwaliteitscontrole en AS en T.
- QA Operationele Uitmuntendheid.
- Initiëren en stimuleren van het lokale wervingsproces.
- Lijnverantwoordelijkheid en dagelijkse walkthrough.
- Leid OpEx-projecten.
- Onderzoek naar Afwijking, OOX, Klachten.
- Definiëren en implementeren van GPA's.
- Ondersteuning van overdrachtsprojecten en validatiestudies.
- Volg teamstatistieken en zorg ervoor dat KQI /KPI aan de vereisten voldoet.
- Tekst en ontwerp controleren en goedkeuren.
- Rapportage van HSE-incidenten en follow-up van acties.
- Ondersteuning voor inbedrijfstelling van nieuwe apparatuur (OQ, PQ).
- Definieer verbeterpunten in proces en producten.
- Planning van middelen en capaciteit (mensen en apparatuur) en werklastbeheer.
- Performance en leiderschap Ondersteuning aan specialistisch team.
- Zorg voor de beschikbaarheid van apparatuur, chemicaliën en verbruiksartikelen, indien van toepassing.
- SOP-beoordeling en -revisie.
- Voer lokale training uit en controleer de trainingsstatus.
- Melding van technische klachten / bijwerkingen / scenario's voor speciale gevallen met betrekking tot Novartis-producten binnen 24 uur na ontvangst
- Distributie van monsters voor het in de handel brengen (indien van toepassing)

Key Performance Indicators

- Succesvolle ondersteuning van projecten met afgesproken kwaliteits- en opleverdata, passeren van interne en externe inspecties
- Voldoen aan de kwaliteit en tijdlijnen voor alle projecten
- Handelen in overeenstemming met GMP, ethische, gezondheidsveiligheid en milieu (HSE) en informatiebeveiliging (ISEC)
- Het aantal en de ernst van cGMP-problemen die tijdens interne en externe audits zijn geïdentificeerd
- Eindejaarscijfers binnen budget

Work Experience

- Kritieke onderhandelingen
- People Leadership
- Operationeel management en uitvoering
- Grensoverschrijdende samenwerking
- Projectmanagement

Skills

Prestatie-evaluaties van werknemers
Personeelsbeheer
Qa (Kwaliteitsborging)
GMP-procedures
Controle beheer
Besluitvormingsvaardigheden
Gereedheid voor inspectie
Productrelease
Organisatorische vaardigheden
People Management en Leiderschap
Communicatieve vaardigheden
Omgaan met ambiguïteit
Zelfbewustzijn
Continu leren
Technologische expertise

Language

Engels

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

Schaftenau

Company / Legal Entity

AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area

Quality

Job Type

Full time

Employment Type

Regelmatig

Shift Work

No

```
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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"]) {
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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:
```

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false, playlistEvents: false, castEvents: false } };
```

```
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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/nl-NL/NovartisCareers/job/Schaftenau/Senior-QA-Operations-Expert--Qualified-Person--m-f-d-REQ-10074153-2>
4. <https://novartis.wd3.myworkdayjobs.com/nl-NL/NovartisCareers/job/Schaftenau/Senior-QA-Operations-Expert--Qualified-Person--m-f-d-REQ-10074153-2>