

## 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

- 跨站点的质量操作监督。
- 入站QA监督。
- 出站 QA 监督。
- MBR 审查和批准。
- 产品发布。
- 质量控制和 AS 和 T 的 QA。
- QA 卓越运营。
- 启动并推动本地招聘流程。
- 线路责任和日常演练。
- 领导运营项目。
- 偏差调查, OOX, 投诉。
- 定义并实施 CAPA。
- 支持转移项目和验证研究。
- 跟踪团队指标并确保 KQI/KPI 满足要求。
- 审查和批准文本和设计。
- HSE 事件报告和行动跟进。
- 新设备调试支持(QQ, PQ,)
- 定义工艺和产品的改进领域。
- 资源和能力人员和设备规划和工作量管理。
- 对专业团队的绩效和领导力支持。
- 酌情确保设备、化学品和消耗品的供应。
- SOP 审查和修订。
- 执行本地培训并监控培训状态。
- 收到后 24 小时内报告与诺华产品相关的技术投诉/不良事件/特殊情况  
(营销样本的分发适用)

## Key Performance Indicators

成功支持具有商定质量和交付日期的项目,通过内部和外部检查  
满足所有项目的质量和时间表  
根据GMP,道德,健康安全和环境HSE和信息安全IS&EC衍事  
内部和外部审核期间发现的cGMP问题的数量和严重程度  
预算内的年终数字

## Work Experience

关键谈判  
领导力  
运营管理和执行  
跨界协作  
项目管理

## Skills

员工绩效评估  
人员管理  
QA(质量保证)  
GMP程序  
审计管理

决策能力  
检查准备  
产品发布  
组织能力  
人员管理与领导力  
沟通技巧  
处理歧义  
自我意识  
持续学习  
技术专长

Language

英语

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

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

正式

Shift Work

No

```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6a3840bd2d3aa302000367", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, muted: false, loop:
false }, sources: { options: {}, startTime: 0 }, disableUserCache: "true", plugins: {}, sources: { options:
{}}, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu:
false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets:
['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
kPlayer.ui.components.Remove } ] } }; // Check and add plugins only if they exist if
(kPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if
(kPlayer.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 (kPlayer.plugins["preventSeek"]) {
config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; }
config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation =
{ position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if
(kPlayer.plugins["hotspots"]) { config.plugins["playkit-js-hotspots"] = { disable: true }; } if
(kPlayer.plugins["moderation"]) { config.plugins["playkit-js-moderation"] = { disable: true }; } if
(kPlayer.plugins["info"]) { config.plugins["playkit-js-info"] = { disable: true }; } if
(kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if
(kPlayer.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 } }; }
```

```
// Ensure the global player registry array always exists, regardless of embed type.  
window.kalturaPlayerVideos = window.kalturaPlayerVideos || []; try { var kalturaPlayer =  
kPlayer.setup(config); // Add the player to the global array.  
window.kalturaPlayerVideos.push(kalturaPlayer); // Load the Player for other media.  
kalturaPlayer.loadMedia({entryId: "1dgfvmafo"}); } 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/zh-CN/NovartisCareers/job/Schaftenau/Senior-QA-Operations-Expert--Qualified-Person--m-f-d-REQ-10074153-2>
4. <https://novartis.wd3.myworkdayjobs.com/zh-CN/NovartisCareers/job/Schaftenau/Senior-QA-Operations-Expert--Qualified-Person--m-f-d-REQ-10074153-2>