

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 \(PDF 30 MB\)](#)

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 config = { targetId: "kalturaplayer6a1ae2b39fd3d900466447", provider: { widgetId:
"1Qm7rm1pm", 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/novartis.com/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>