

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

Job ID
REQ-10074153
апр 15, 2026
Австрия

Сводка

#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 (OQ、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 (ISEC) 行事
- ~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 \(PDF 30 MB\)](#)

Дивизион
Operations
Business Unit
Quality
Место
Австрия
Сайт
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

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