NOVARTIS

QP Quality Lead Pilot

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Сводка

The QP Quality Lead Pilot Plant is responsible for providing strategic quality leadership and Qualified Person (QP) oversight for the TRD GDPD Pilot Plant in Schaftenau, Austria. The Pilot Plant performs assembly, testing, storage, and technical release for drug device combination products including technical, stability and clinical batches. The pilot plant team is responsible for the transfer of the process as well as analytical methods to commercial operations.
This role serves as the primary quality leader for Pilot Plant operations and associated laboratories, ensuring compliance with cGMP, GDP, ISO 13485, FDA 21 CFR Part 4, 21 CFR Part 820/QMSR, EU MDR 2017/745 and other applicable global regulatory requirements.
The position provides independent quality decision-making, leads regulatory inspection readiness activities, drives continuous improvement of the Quality Management System, and acts as the Qualified Person for certification and release activities as applicable.

About the Role

Major Accountabilities:

- Serve as Qualified Person (QP) for Pilot Plant operations
- To serve as a Qualified Person (QP) under Austrian law (AMBO 2009), all requirements listed in §7 of AMBO must be met
- Provide independent quality oversight for manufacturing, testing, warehousing, and release activities.
- Ensure compliance with Novartis Quality Standards and applicable global regulatory requirements.
- Act as a final quality decision maker for critical quality and compliance issues.
- Establish, maintain and continuously improve a robust Quality Management System aligned with GxP, FDA 21 CFR Part 4, FDA 21 CFR Part 820/QMSR, EU MDR 2017/745, ISO 13485, ISO 14971.
- Support health authority inspections notified body audits, self-inspections and customer audits.
- Provide QA oversight for manufacturing, testing, technical batch release, GMP laboratories, warehousing, qualification and validation activities.
- Ensure effective management of deviations, OOX/OOS events, complaints, CAPAs, change controls and risk assessments.
- Routine tasks focus on QA oversight of manufacturing, batch record review, failure investigations and deviation, change controls, and release activities. Ensure that compliance with cGMP/ GxP is maintained in TRD (Technical Research and Development).
- Partner with GDPD Pilot plant, Manufacturing, Technical Development, Regulatory Affairs, Device Development, Engineering and Supply Chain functions.
- Coach and mentor quality associates while fostering a culture of compliance and continuous improvement.

Minimum Requirements:

- Master's Degree in Pharmaceutical Sciences, Biotechnology, Engineering, Chemistry, Life Sciences or related discipline.
- Qualified Person certification according to Directive 2001/83/EC
- Minimum 8 years of experience in Quality Assurance, Manufacturing or Quality Compliance within the pharmaceutical, medical device or combination product industry.
- Demonstrated experience acting as a Quality Lead within GMP-regulated environments.
- Experience supporting or leading health authority inspections and audits.
- Experience with clinical supply manufacturing and release activities preferred.
- Experience with drug-device combination products strongly preferred.

Technical Expertise

- Qualified Person (QP)
- Validation and qualification principles
- Data Integrity
- Drug-Device Combination Products

Leadership Competencies

- Strategic leadership, Quality decision making, Stakeholder management, Communication Skills, Continuous Improvement mindset, Data integrity, Dealing with Ambiguity, Digital savviness, Problem Solving Skills, Regulatory Requirements knowledge, Collaboration

Language Skills

- Fluent English and German (written and spoken).

Benefits & Rewards

At Novartis, we’re committed to reimagining medicine together - and rewarding the people who make it happen.

Expected Annual Base Salary Range for role: €85,300 to €158,300

The base salary offered is determined based on gender-neutral objectives, such as relevant skills, competencies and experience in accordance with the Novartis pay setting policy and upon joining Novartis will be reviewed periodically.

In addition to your base salary, you may be eligible for a performance-based bonus depending on certain performance parameters.

The rewards of being part of our team go far beyond base pay and incentives. We also offer a variety of competitive benefits in kind to help you thrive personally and professionally, such as insurance plans, retirement plans, wellbeing resources and global recognition programs. In addition, we provide flexible and hybrid working options, where possible, and minimum 14 weeks paid parental leave.

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
Дивизион
Development
Business Unit
Quality
Место
Австрия
Сайт
Schaftenau
Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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List of links present in page

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2. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
3. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Schaftenau/QP-Quality-Lead-Pilot_REQ-10082990
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