Research & Development QA Team Lead

Job ID
REQ-10059002

8月 04, 2025

Austria

摘要

LOCATION: Schaftenau, Austria
ROLE TYPE: Hybrid Working, #LI-Hybrid

The Quality Team Lead (Technical Research & Development (TRD) Drug Delivery System (DDS) Quality Assurance (QA) is responsible for leading and managing a team of 4-10 quality associates, both locally and at selected remote sites, with a primary focus in Schaftenau.

This role guides and supports the team to ensure comprehensive quality oversight of all assigned medical device development projects while managing resources, budgets, and fostering a culture of continuous improvement. The Team Lead provides quality expertise and strategy alignment with TRD and Technical Operation partners, ensures governance of labs and business processes, and drives operational excellence in the TRD Assembly pilot plant and Good manufacturing Practice (GMP) In Process Control and release lab. The position also prepares the team for audits and inspections and represents TRD DDS QA locally and globally on quality matters.

About the Role

Key Responsibilities

Team Leadership and Development

- Lead, mentor, and develop a team of 4-10 direct full-time equivalent (FTE) quality associates through guidance, coaching, and performance management to enhance team competencies and capabilities, fostering a culture of quality, high performance, and trust.
- Guide and support team members to ensure effective quality oversight on assigned medical device development projects.
- Promote operational excellence in the TRD pilot plant for medical device assembly and its GMP lab.
- Prepare and guide the team for on-site audits and inspections to ensure regulatory compliance.
- Drive TRD QA strategy in close alignment with business partners and TRD QA platform leadership.
- Represent TRD DDS QA on site and interact with local Health Authorities, Notified Bodies, and global teams.
- Be accountable for QA release activities and management of the CMC project portfolio.
- Contribute to global project strategies, contingency planning, and risk assessments and engage with local and global stakeholders, integrating diverse perspectives for optimal outcomes

Qualifications

Education

- Bachelor ' s degree with minimum 10 years ' experience in pharma quality or operations, or Master ' s degree with minimum 5 years ' experience in pharma quality or operations. A PhD is beneficial.
- At least 3 years ' experience in people management.
- Comprehensive knowledge of drug substance, drug product, and medical device development, assembly, and manufacturing.
- Deep understanding of quality standards and policies, including 21 CFR part 4, part 820, part 11, ISO 13485, MDR requirements, EU GMP regulations, and related international guidelines.
- Experience with Health Authority Inspections (especially FDA and EMA) and Notified Body audits.
- Proven experience leading, managing, or supervising a team of at least 4 associates in a regulated environment.
- Broad experience in technical drug development, Quality Assurance and/or Quality Control departments; Technical Operations or equivalent experience from external companies preferred.
- Knowledge of RegCMC requirements for Health Authority submissions (INDs, IMPDs, NDAs, ANDAs, MAAs).

Languages

- Fluent English required (oral and written).
- Proficiency in the local site language desired (oral).

Additional Requirements

- Proven track record in successfully leading interdisciplinary teams, such as scientists working on technical or methodological projects.
- Extensive expertise in interpreting applicable regulations and guidelines.
- Profound knowledge and training of all product types detailed in the current Site Master File manufactured on site.

You ' ll receive:

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In addition to a market-competitive base salary, we offer an attractive incentive program, a modern company pension scheme, childcare facilities, learning and development opportunities as well as worldwide career possibilities within the Novartis group. In accordance with Austrian law, we are obliged to disclose the minimum salary as stated in the collective bargaining agreement. For this position the minimum salary is € 55.700/year (on a full-time basis).

We also offer a potential market oriented excess payment in line with your experience and qualifications.

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive working environment and diverse teams, representative of the patients and communities we serve.

Adjustments for Applicants with Disabilities:

If because of a medical condition, physical disability or a neurodiverse condition you require an adjustment during the recruitment process, please reach out to disabilities.austria@novartis.com and let us know the nature of your request as well as your contact information. The support which we can provide will include advice on suitable positions as well as guidance at all stages of the application process. Austrian law provides candidates the opportunity to involve the local disability representative, Behindertenvertrauensperson (BVP), in the application process. If you would like to request this, please let us know in advance as a note on your CV.

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部门
Development

Business Unit
Innovative Medicines

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
Regul ä r

Shift Work
No

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