R&D Senior Quality Manager Data & Digital

Job ID
REQ-10061301

9月 02, 2025

Austria

摘要

The Senior Quality Manager Data & Digital Technical Research & Development (TRD) Quality Assurance (QA) oversees the incorporation of new technologies in TRD and the implementation of digitalization strategies in business processes.

The role incumbent reports into the TRD QA platform and represents QA in the respective modality. They are a direct member of the TRD QA Data & Digital (D&D) Network and the TRD digital Chemical Manufacturing Control (CMC) accelerator team. They oversee the function specific D&D portfolio and, act as global business process owner for Biologics (Bx)/Cell & Gene Therapies (CGT) QA in Spine and Strive. They drive global digital projects and also, provide quality assurance expertise, guidance and support to operational activities in development and research organizations to ensure compliance with applicable regulatory requirements and Novartis procedures and quality standards. They will manage projects, including Quality Plan initiatives, and processes that support quality objectives to assure their compliance with Good Practice (GxP) regulations.

About the Role

Major accountabilities:

Represents the TRD QA Bx platform in the TRD QA Data & Digital Network

- Acts as GPO (Global Process Owner) for QA in the own QA platform. Is QA member of the digital CMC accelerator team (Strive and SPINE). Drives cross-platform alignment.
- Owns and drives the Data & Digital portfolio for QA as partner of the respective TRD functions (close partnership with the line function Specialist Point of Contact (LF SPOCs) in TRD). Ensures the LF portfolio is covered within the global TRD QA Data & Digital portfolio.
- Is accountable for QA oversight during project execution in function specific and x-functional projects. Supports the global platform head and the TRD QA data & digital network lead to ensure appropriate staffing of respective improvement projects.
- Ensures that Data & Digital projects / tools impacting TRD and/or TRD QA are well supported during ideation, execution and implementation phases. Takes accountability for driving Good Manufacturing Practice (GMP) compliant change control execution and ensures close partnership with the respective e-compliance teams.
- Ensures direct and close communication within the own TRD QA platform and to other TRD QA platforms.

Leads complex global Data & Digital projects directly or contributes as TRD QA representative.

- Is a member of global TRD and/or Research & Development Quality (RDQ) Data & Digital Projects as TRD QA SPOC.
- Has a solid understanding of the respective GMP business process and ensures end to end (E2E) oversight of the data flow. Is accountable for QA oversight of the business process changes including potential QMS updates.
- Holds the team accountable for GMP compliant change control execution.
- For complex projects with more than one TRD QA member: Leads the TRD QA subteam and ensures “one voice” decision making.

Contributes to the TRD QA own Data & Digital agenda including organizational upskilling

- Fosters Artificial Intelligence (AI) usage in TRD QA, acts as an ambassador for the TRD digitalization journey and the extended use of AI tools in TRD in a GMP compliant manner.
- Being part of TRD QA D&D Exchange Network and participate TRD QA D&D Review Board and supports TRD QA D&D portfolio oversight management (Mission control).
- Contributes to the know-how exchange with external partners to strongly support the Novartis digital and AI journey (RDQ Gen AI network).
- Develops individual quality know-how to enable extended use of AI tools in TRD in a GMP compliant manner. Provides functional expertise to part-time members within the TRD D&D QA platform.
- Proposes and owns digital projects to improve ways-of-working in TRD GMP areas and within TRD QA.
- Support maintenance of the regulatory-required files for health authority inspections and assist with health authority inspection management

- Support generation of Quality Plans (and review other plans for quality/safety aspects)
- Aid in the identification of quality issues and assist with root cause investigations and Support the development of corrective and preventative action plans (CAPA), including monitoring status to Ensure issues are addressed, completed and documented.

Key performance indicators:

- Quality (GMP), quantity and timelines for all assigned tasks/projects
- Compliance with Novartis standards, in particular ethics, health, safety information security (ISEC)
- Achieve key milestones of TRD QA (cross-functional taskforces and initiatives). All Data & Digital projects with GMP relevance for TRD and/or TRD QA are appropriately staffed and executed.
- Measurable contributions to the success, growth, efficiency and productivity of TRD QA and new Data & Digital / AI programs / initiatives started and implemented
- Timely and targeted communication within TRD QA and towards relevant stakeholders

Minimum Requirements:

- 5+ years of relevant experience in development quality environment.
- Successfully demonstrated experience in project management or operations management. Proven track-record of successfully managing interfaces to other functions.
- Strong quality background. Excellent track-record of innovation within Data & Digital, problem solving and productivity in projects, ideally IQP green belt certification. Strong IT / AI skills desired.
- Strong interpersonal skills, including diplomacy and persuasion, used in obtaining cooperation and consensus with Novartis colleagues, vendors and customers.
- Functional Breadth.
- Critical Negotiations.
- Project Management.
- Collaborating across boundaries.

You ' ll receive:

You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

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 €65,605.54 /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.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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
Regular

Shift Work
No

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