

Country Quality Manager & Qualified Person

Job ID

REQ-10089052

Sep 30, 2026

LOC_TR

About the Role

Major Accountabilities:

- Manage the implementation and maintenance of a local Quality Management System that complies with local regulatory requirements and the Novartis Quality Manual and policies.
- Ensure timely implementation of updates to applicable local guidelines and requirements, including GMP, GDP, and barcode and 2D barcode requirements for human medicinal products.
- Fulfil the duties and responsibilities of the Qualified Person for the Farmanova entity, including performing batch release checks and approving relevant products.
- Perform release activities for supporting clinical products.
- Approve artwork changes for Farmanova products.
- Collaborate with all Country functions responsible for GxP and health-regulated activities to ensure the efficient and effective operation of the Country Quality System.
- Establish and maintain effective communication with local Health Authorities and the Country organisation, ensuring that all commitments are appropriately tracked and closed on time.
- Manage product recalls/ mock recalls in accordance with local regulatory requirements and the Novartis Quality Manual, and support or participate in related activities as required.
- Participate in the evaluation and investigation of quality deviations and complaints, ensuring that appropriate corrective and preventive actions (CAPAs) are established.
- Lead escalation processes and follow up on required actions.
- Review and approve standard operating procedures (SOPs).
- Manage changes that affect or could affect product quality and serve as the Change Management Lead for the Country organization.
- Perform Marketing Authorisation Holder (MAH) reviews of relevant Annual Product Quality Reviews (APQRs), prepare the annual APQR plan, evaluate trends, and follow up on actions.
- Ensure the annual Quality Plan is prepared, and its actions are followed through to completion.
- Lead Quality System and GMP audits conducted by Health Authorities, Novartis Global functions, or outsourced service providers.
- Lead training and self-inspection activities in accordance with local and global requirements.
- Ensure compliance with quality risk management requirements, including the identification, anticipation, and assessment of quality risks; development and implementation of appropriate action plans; and preparation of the annual risk assessment plan and report.
- Report quarterly Key Quality Indicators within the scope of responsibilities, monitor performance, and ensure that gaps are appropriately addressed to mitigate risk.· Prepare annual and quarterly review reports, including the Annual Quality Review Report, Training Plan Report, and Business Review Meeting materials.
- Provide quality oversight of the third-party warehouse and maintain effective collaboration with relevant partners.
- Lead vendor management activities, including quarterly review meetings, preparation of the Approved Supplier List, qualification processes, and Quality Assurance Agreement (QAA) preparation.
- Actively drive operational excellence projects in alignment with global process streams and the Country Quality strategy.
- Ensure implementation and maintenance of the ISO 9001:2015 Quality Management System within the Türkiye Country organization.·
- Act as the Quality Operations Partner (QOP) single point of contact within the Country Quality organization.·

- Serve as Culture Ambassador Lead for Country Quality Türkiye within the region. ·
- Act as deputy to the Country Quality Head Türkiye.

Key Competencies

- Proactive mindset
- Resilience and adaptability
- Business acumen
- Curiosity and continuous learning
- Sound judgement and decision-making
- Strong project management skills

Role Requirements

- University degree in Pharmacy, Chemical Engineering, Chemistry, or a related discipline.
- Advanced written and verbal communication skills in English are required.
- At least 6 years of Quality experience within the pharmaceutical industry.
- At least 2 years of experience at a pharmaceutical manufacturing site in Quality Control, Quality Assurance, or Manufacturing Quality.
- Strong knowledge of the regulations, guidelines, and good practices applicable to Country organisation operations.
- End-to-end process orientation and a continuous-improvement mindset.
- Strong knowledge of current Good Manufacturing Practice (cGMP), relevant GxP requirements, and pharmaceutical distribution processes.
- Ability to manage multiple priorities and consistently meet deadlines.
- Excellent interpersonal, communication, and presentation skills.

Role Requirements

Division

DIV_TO

Business Unit

Quality

Location

LOC_TR

Site

Istanbul Ataşehir

Company / Legal Entity

TR01 (FCRS = TR001) Novartis Sağlık, Gıda ve Tarım Ürünleri San. Ve Tic. A.Ş.

Functional Area

FCT_QA

Job Type

Full time

Employment Type

Regular

Shift Work

No

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