

Country Quality Manager & Qualified Person

Job ID
REQ-10089052
Сен. 30, 2026
Турция

Сводка

- To ensure that the product, processes and procedures conforms with GxP and local specifications and that production activity is compliant with Novartis quality policy and GxP requirements.
- To ensure that relevant documentation is up-to-date and archived correctly. Ensure "state of the art" GxP know-how and future trends in the field of GxP

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.
- Fulfill 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.

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>

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Дивизион
 Operations
 Business Unit
 Quality
 Место
 Турция
 Сайт
 Istanbul Ataşehir
 Company / Legal Entity
 TR01 (FCRS = TR001) Novartis Sağlık, Gıda ve Tarım Ürünleri San. Ve Tic. A.Ş.
 Functional Area
 Quality
 Job Type
 Full time
 Employment Type
 Regular
 Shift Work
 No

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