

Quality Assurance Specialist

Job ID REQ-10038364 Jan 29, 2025 Türkiye

Summary

Manages Quality aspects and projects within area of responsibility. Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems.

About the Role

Major accountabilities:

- Manage the implementation of a local quality system that complies with the requirements of the regulatory and Novartis corporate quality manual & policies
- Support the batch release checks & approval of the products
- Coordinate with all concerned Country functions responsible for GxP and health-regulated activities to ensure the efficient and effective operation of the Country Quality System
- Leading the quality incidents
- Involve in quality deviations & complaints evaluation and investigation; ensure the appropriate CAPAs are in place
- Acting as key user of ESOPs (SOP Tool) and Condor system (Document Management Tool)
- Preparing procedures
- Manage all changes that affect or could affect the product quality
- Management of product destruction process from quality perspective
- Management of training activities for GxP functions
- To support the Quality System / GMP audits by health Authorities, Novartis Global functions or outsource companies
- Support on all QMS items (trainings, self inspections, site-master file preparation etc.)
- Report monthly Key Quality Indicators within scope of responsibilities, monitor them and assure that gaps are addressed appropriately in order to mitigate risk
- Preparation yearly/quarterly review reports
- Ensure ISO 9001:2015 Quality Management System implementation in Country Organization Turkey

Essential Requirements:

- University degree in Pharmacy, Chemical Engineering or Chemistry
- Strong Communicator in English and local language
- Minimum 3 years of experience in Quality Assurance department
- Experience in other functions (Manufacturing, Quality Control, Validation, Warehousing ie.) and/or knowledge of Country Quality operation is considered advantageous
- Strong knowledge of cGMP
- Able to multitask and meets deadlines

- · Continuous Learning
- Being resilient
- · Business Insight
- Curious
- Negotiation Skills
- GMP Procedures
- Managing Complexity

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

Benefits and Rewards:

Read our handbook to learn about all the ways we'll help you thrive personally and professionally: Novartis Life Handbook

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to learn more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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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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

Division

Operations

Business Unit

Innovative Medicines

Location

Türkiye

Site

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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