Country Quality Assurance Manager

Job ID
REQ-10028130
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Résumé

Location: Cairo, Egypt #LI-Hybrid

About the Role:

As a Country Quality Assurance Manager, you will be responsible to ensure that the product quality conforms with the set standards and specifications, and that production activity is compliant with Novartis Quality Policy and GxP requirements. Ensure that relevant documentation is up-to-date and archived correctly. Ensure the “state of the art” GxP know-how and future trends in the field of GxP.

This role reports directly into the Country QA Head.

About the Role

Key Responsibilities:

- Ensure that all aspects of the handling, manufacturing and distribution of biopharmaceutical / pharmaceutical products are in compliance with the Novartis Quality Manual, the effective Quality Agreement that they meet relevant GxP regulatory requirements and are conducted according to local SOPs.
- Prepare, review and check the batch documentation for correctness, completeness and safely archive the original documents for the prescribed period and plan, conduct and monitor self-Inspection schemes for all sections.
- Monitor actions and corrections accordingly. Conduct GxP monitoring on all sections, conduct QA investigation for noncompliance, follow up the corrective actions.
- Archive relative documentations and manage/Approve critical quality issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc.) according to the Quality Agreement and the Novartis Quality Manual.
- Ensure investigations are correctly executed. Ensure all required actions are taken appropriately and in a timely fashion. Escalate any issues or instances of instability per the Novartis escalation policy and initiate any market action that is required.
- Decide escalation to Senior Management Level and lead Global Quality Assessments and manage filing accordingly as well as ensure that Change requests, are managed according to the Novartis SOPs from receipt, through to the implementation and closure.
- Responsible for assessing quality trends and driving continuous improvement for processes and product quality performance and maintaining access to regulatory and pharmaceutical authorities in respect to up-dated GxP, providing latest know how in the field of GxP and other quality related fields.

- Identify repetitive activities and regulatory areas for which SOPs are required. Initiate the introduction of SOPs. Plan, initiate and monitor basic GxP-training for all employees in regular intervals. Responsible for annual training program and implementation.
- Establish and maintain cross-functional contacts with peer organization and authorities and, follow-up quality related developments in the field of pharmaceutical products -Support launches of product in close collaboration with BD and L partner and/ or development organization.
- Ensure that all drug products are released to the market in accordance with the registered specifications and with local/international regulations. Ensure that coordinated contact is maintained with all parties (the Regulatory Authorities, the local partners and stakeholders and Global QA. Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Essential Requirements:

- 5-8 years of relevant experience in Quality or relevant GxP Area (i.e., Regulatory, Supply Chain, Technical Operations, Patient Safety) in Multinational Companies.
- Pharmacist.
- Strong English language proficiency.

Desirable Requirements:

- Experience in above-country stakeholder management.

Commitment to Diversity and Inclusion:

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

Novartis is a proud member of the *ILO Global Business and Disability Network* and the *Valuable 500,* promoting the inclusion of people with disabilities in workplaces around the world. We also collaborate with international partners, such as *Disability: IN*, *Purple Space,* and *Business Disability Forum* to identify and develop best practice solutions to enable people with disabilities to participate as equal members of our organization.

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Skills:

- Change Control.
- Continuous Learning.
- Dealing With Ambiguity.
- Guideline.
- Product Release.
- QA (Quality Assurance).
- Quality Management.
- Regulation.
- Risk Management.
- Self-Awareness.
- Technological Expertise.

Languages:

- Arabic.
- English.

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

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Business Unit
Innovative Medicines
Emplacement
République arabe d'Egypte
Site
New Cairo
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Functional Area
Qualité
Job Type
Full time
Employment Type
Regular
Shift Work
No
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