QC Specialist II _ Micro

Job ID
REQ-10030203
Nov 17, 2024
China

About the Role

About the role:

- As per the local project schedule to strictly complete and follow up QC actions/tasks timely. Escalate issue and work with internal and external stakeholders to resolve issue.
- Lead and complete equipment PQ in micro lab, analytical method transfers and method validation. Manage QC utility, standards, solvent, reagents, etc. to keep safety stock in lab and no impact will be caused by lacking or nonconformance. On time complete environmental monitoring test, water and gas test. Complete method validation protocol and report timely.
- Good communication and collaboration with global QC and AS&T experts to guarantee local quality milestones can be achieved.
- Initiate local QC procedures (e.g., SOPs, WI, Form, analytical method, etc.). On time complete testing for validation samples. Complete lab investigation if any OOX and/or deviation is occurred.
- Support audit and inspection; As the function SME to answer question from auditor and/or inspector without critical findings. Function representative to be involved in global and/or local project if any
- Introduction of new technologies; drives implementation of new requirements. Ensure QC activities executed according to cGxP standards
- Promote and improve the Safety and Quality cultures, by implementing the necessary systems and actions in line with the evolution of the project
- Ensure overall inspection readiness for area of responsibility. Guarantee the effectiveness of the Business Continuity Plan
- Being part of the project crisis management team and depending on skills, expertise and experience can be appointed to one of the NEM roles (Novartis Emergency Management). By delegation of the project Manager may be required to take decisions and take the necessary actions, in particular within the framework of the on-call management system.
- Might run shifts to support product release according to business needs. Responsible for participating in initial training and retraining. HSE incidents reporting & action follow-up

Key Responsibilities

- Minimum : 5-8 years’ experience in the field of Quality Control micro aspect in a pharmaceutical industry environment or equivalent
- University degree in Pharmacy, Engineering, Chemistry, Biotechnology or equivalent
- Fluent (oral and written) in English; local language desired
- Advanced communication skills; motivates colleagues and co-workers
- Being Resilient; Stakeholder Engagement; Operational Excellence; Applied Business Insights
- Risk Management. Audit Management; Health Authorities; Technical Launch and Transfer. Collaboration;

result-oriented
- Expertise in GxP operations; Strong analytical background.
- MS Office applications and other standard IT applications supporting Quality activities

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Role Requirements

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Division
Operations
Business Unit
Innovative Medicines
Location
China
Site

Haiyan (Zhejiang Province)
Company / Legal Entity
CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.
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Job Type
Full time
Employment Type
Regular
Shift Work
No
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