NOVARTIS

QC and AS&T Lead

Job ID
REQ-10030198
Nov 17, 2024
Cina

Sommario

To provide Quality Control and management expertise for the China RLT project in all quality related matters and to ensure that key aspects of the operational business comply with cGMP and regulatory requirements as well as the key Novartis corporate quality policies.
Role model with the Novartis technical expert framework and cultural aspirations. Might provide on shift support to ensure product quality compliance according to business needs

About the Role

Major accountabilities:

- 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. Complete Ch.P gap assessment in 2025
- Lead and complete QC equipment PQ, 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 non-conformance. Manage stability sample and complete relevant test as per plan
- Good communication and collaboration with global QC and AS&T experts to guarantee local quality milestones can be achieved.
- Complete method validation protocol and report timely. 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 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
- Lead team and coaching talents. Ensure the consistency between career development processes and the business strategy
- Ensure that associates are qualified for a GMP task prior to independent performance. Monitor overall training compliance for in-scope associates

Essential Requirements:

- 8-10 years professional experience in the field of GMP QC with Sterility Product Manufacturing 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

- Current Pharmacopoeia and GxP requirements, relevant official guidelines and regulations (e.g. FDA, EU, ICH, etc.) and TQM with regard to the area of Quality Control and Quality Assurance
- Expertise in GxP operations; Strong analytical background.
- MS Office applications and other standard IT applications supporting Quality activities
- Collaboration; result-oriented. Budget management, Risk Management. Advanced communication skills; motivates colleagues and co-workers. Leadership and change management, objective setting and performance management. Highly structured working style.
- Applied Business Insights, Project Excellence, Stakeholder Engagement, Organizational Savvy

Desirable Requirements:

- Professional experience on analytical test method development/transfer and validation
- Project management, Operations Management and Execution, People Leadership, Collaborating across boundaries, Functional Breadth, Project Management, Financial Management, Industry/ Business Exposure.

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Divisione
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Posizione
Cina
Sito
Haiyan (Zhejiang Province)
Company / Legal Entity
CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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

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