NOVARTIS

Lead, QSRC (Quality System Regulatory Compliance)

Job ID
REQ-10025792
Nov 03, 2024
Singapore

About the Role

Key Responsibilities:

- Leads the Quality Systems, Regulatory and Compliance team. Manages team in day-to-day work activities and priorities to set and deliver team's operational
- targets and compliance with all health, safety and training procedures or requirements.
- Develops objectives for implementation of strategies and plans for site Quality Systems, Regulatory & Compliance team. Develop, coach, mentor and engage
- team to build a high performance team to meet team and group objectives.
- Ensures that site's quality systems, compliance systems, and regulatory systems are established and maintained to support site operations.
- Cultivate site's quality, data integrity and speak-up culture.
- Active member for network harmonization teams and best practice platform establishment
- Leads the site establishment, maintenance and continuous improvement of esignated Novartis quality systems and related procedures, and ensure that the systems comply with Novartis policies, standards & procedures, and international regulatory and legislative requirements, as required.
- Provide quality oversight on the department's GMP training to ensure that for department's GMP training complies with Novartis and local quality requirements.
- Leads the management of site's systems/ procedures related to regulatory activities, and maintenance of site's regulatory relevant licenses and permits as required, including supporting site in setting standards with regulatory relevant information included in both local and international regulatory / legislative requirements, as required.
- Leads the management of site inspection related activities, such as, but not limited to, (1) inspection readiness activities, (2) internal audit programs (Compliance Walkdowns / Self-Inspections / Corporate Audits) and/or (3) external inspections (Clients / Health Authorities). Leads the management of post inspection responses / actions and follow up with action owner(s) to ensure such responses / actions meets requirements and committed timelines.

Essential Requirements:

- 12-15 Years of experience in Pharmaceutical Manufacturing with adequate experiences in QA Compliance / Quality System and Management role.
- Proven track record/practical experience in leading a quality section to ensure full compliance with global cGMP requirements. Successfully managed authority inspections from major HA's e.g. FDA, EMA, HSA.
- Collaboration; result-oriented; problem-solving-oriented
- Advanced communication skills; motivates colleagues and co-workers

- Maintains exchange of experience Leadership and change management, objective setting and performance management.
- Budget management, Operational Excellence, Risk Management. Project Excellence Stakeholder Engagement; Organizational Savvy.
- Applied Business Insights. Additional qualification in the GMP area. Quality Assurance, Knowledge of GxP, Health Authorities, Supplier.
- Relationship Management; Strategic thinking and planning; Quality

Desirable Requirements:

- University degree with a scientific / technological background (e.g. Chemistry, Pharmacy, Biology, Biochemistry, or equivalent)

Role Requirements

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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Division
Operations
Business Unit
Innovative Medicines
Location
Singapore
Site
Tuas South Avenue
Company / Legal Entity
SG12 (FCRS = SG012) Novartis Singapore Pharmaceutical Manufacturing Pte Ltd
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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