

Expert - QSRC

Job ID
REQ-10061544

9月 09, 2025

Malaysia

摘要

-Manage cost effective GxP Compliance and/or Audit activities, operations and systems to ensure compliance of business areas with the Novartis Quality Manual and Policies and all relevant GxP, legal and regulatory requirements, and through internal audits, KPIs (Key Performance Indicators) and KQIs (Key Quality Indicators) -Performs preparation and management of external and corporate audits and Health Authority inspections.

About the Role

Major accountabilities:

- Planning and supporting PQR/APQR activities.
- Support site qualification and validation activities (planning, advising, review).
- Implementation of Quality Systems (incl. documentation management) -Supplier management activities (agreements, oversight, audit).

- Preparation/support and coordination of CAPA/follow-up -Audit and inspection preparation and support -Change control review/approval -Ensure local DI and eCompliance oversight (training, inspections, plan, risk ID etc) -Ensure process quality assurance acc.
- to regulations -QP declaration review and approval -KPI trending -Ensure applications, certificate maintenance etc. to local HA -SPOC for communication with HA, GCA / One voice /consolidated approach / synergies for all sites within same HA jurisdiction / country -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Successful support of projects with agreed quality and delivery dates, passing of internal and external inspections.
- Meet quality and timelines for all projects -Act in accordance with Novartis standards.
- The number and severity of cGMP issues identified during internal and external audits -Year-end figures within budget; Successful coordination of departmental operational activities

Minimum Requirements:

Work Experience:

- Functional Breadth.
- Collaborating across boundaries.
- Project Management.
- People Leadership.

Skills:

- Audit Management.
- Auditing.
- Communication Skills.
- Compliance Audits.
- Compliance Risk.
- Continuous Learning.
- Dealing With Ambiguity.
- Decision Making Skills.
- Gmp Procedures.
- Inspection Readiness.
- Organizational Skills.
- People Management And Leadership.
- Qa (Quality Assurance).
- Regulatory Compliance.
- Risk Management.
- Self Awareness.
- Technological Expertise.

Languages :

- 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>

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部门

Operations

Business Unit

Universal Hierarchy Node

地点

Malaysia

站点

Selangor

Company / Legal Entity

MY01 (FCRS = MY001) Novartis Corporation (Malaysia) Sdn. Bhd. (19710100054)

Functional Area

Quality

Job Type

Full time

Employment Type
Regular

Shift Work
No

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