

QA Specialist QMS Support

Job ID
REQ-10077198
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Гонконг

Сводка

- Manages Quality aspects and projects within area of responsibility.
- Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems

About the Role

Major Accountabilities:

- Support product release to the market and ensure compliant to registered version
- Ensures the timely collection, monitoring, and reporting of Quality Key Performance Indicators (KPIs) for management reporting
- Assists in Health Authority inspections and internal audits by supplying information and documentation in a timely manner
- Support and track the implementation and maintenance of the local Quality system in accordance with the Novartis Quality Manual
- Manages processes and systems for all GxP Quality Assurance e.g. Change control, Training Management, Escalation Management, Risk Management. Ensures that processes are conducted in full compliance with the GxP and the Novartis Quality.
- Contributes to an improvement of current processes and/or to an implementation of modified processes.
- Ensures adequate tracking and on time completion of corrective and preventive actions (CAPA), inc escalation of issue related to the closure of CAPA, as appropriate.
- Review quality deliverables to ensure compliance, with health authority requirements and SOPs, including procedural documents, records, third party work, contractors, clinical trial material, components, and gap assessments
- Prepare and review GxP documentation; assists in the release of GxP documentation, filing and archiving of GxP documentation
- Supports Compliance review of projects and inspection readiness and management
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt

Key Performance Indicators:

- Quality standards are understood, designed into work activity, and achieved.
- In accordance with departmental objectives such as support of projects with agreed quality and delivery date, passing of internal and external inspections

Work Experience:

- Quality Management Systems
- GxP Experience
- Quality Compliance
- Quality Assurance
- Technological Expertise

Skills:

- Dealing With Ambiguity
- Decision Making
- Project Management
- Risk Management
- Collaboration
- Regulatory requirements knowledge
- Problem Solving Skills
- Leadership
- Communication skills
- Data Integrity
- Digital saviness

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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[Read our handbook \(PDF 30 MB\)](#)

Дивизион
Operations
Business Unit

Development
Место
Гонконг
Сайт
Hong Kong
Company / Legal Entity
HK02 (FCRS = HK002) Novartis Pharma
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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