NOVARTIS

QA Specialist

Job ID
REQ-10080295
Jun 10, 2026
LOC_HK

About the Role

Major Accountabilities:

- Ensure that Change requests, are managed according to the Novartis SOPs from receipt, through to the implementation and closure.
- Conduct GxP monitoring on all sections, conduct QA investigation for noncompliance, Follow up the corrective actions. Archive relative documentations.
- Coordinate implementation of quality system and procedures for the implementation of Novartis Quality Manual and quality agreements.
- Ensure that all aspects of the handling and distribution of pharmaceutical products in the country comply with the requirements of the Novartis Quality Manual and Policies and meet all relevant cGMP regulatory and legislative requirements.
- Ensure that a local Quality System and Standard Operating Procedures are in place for all cGMP/GDP related activities and that compliance with cGMP/GDP regulations is maintained through training and internal audits.
- Maintain current knowledge of local and international regulatory and legislative requirements and trends to ensure that technical support on all quality related matters is provided to the country.
- Establish a good working relationship with the Supply Chain Management (SCM), DRA and Medical departments.
- Ensure that coordinated contact is maintained with the Regulatory Authorities, the local partners (suppliers, third parties, licensees, and distributors) and Global Quality Assurance.
- Ensure that all incoming drug products are inspected prior to release to the market in accordance with the current in place procedures, registered specifications and with local/international regulations.
- Ensure that an effective Change Control process is in place.
- Manage complaints, recalls, counterfeits and product tampering according to the Novartis Corporate Quality Manual and local written procedures. Support / participate in NEM cases as required.
- 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:

- Local GMP/GDP Quality System in place and continuously updated, as required.
- GMP/GDP risks proactively identified and effectively mitigated.
- The number and severity of GMP/GDP issues identified during internaland external audits.

Work Experience:

- Complaints Management
- Product Recall Management
- Quality Management Systems
- Change Control Management
- Deviation Management
- Audit & Inspection Management
- Batch Record Review
- Corrective and Preventive Action (CAPA) Knowledge

- Quality Assurance
- Quality Compliance
- Release Management
- GxP Experience
- SOP (Standard Operating Procedures) development

Skills:

- Analytical thinking
- Leadership
- Communication skills
- Data Saviness
- Digital saviness
- Change Management
- Dealing With Ambiguity
- Good Documentation Practice
- Collaboration
- Regulatory requirements knowledge
- Problem Solving Skills
- Data Integrity

Languages:

- English.

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Division
DIV_TO
Business Unit
Development
Location
LOC_HK
Site
Hong Kong
Company / Legal Entity
HK02 (FCRS = HK002) Novartis Pharma
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Job ID

REQ-10080295

QA Specialist

Apply to Job

Source URL: *https://prod1.jobapi.novartis.com.cn/req-10080295-qa-specialist*

List of links present in page

1. https://prod1.jobapi.novartis.com.cn/req-10080295-qa-specialist
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hong-Kong/QA-Specialist_REQ-10080295
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hong-Kong/QA-Specialist_REQ-10080295