

CPO GMP Quality Manager

Job ID REQ-10068641

12月 17, 2025

Singapore

摘要

Assurance that the product quality conforms with specifications and that production activity is compliant with Novartis quality policy and GxP requirements. Ensure that relevant documentation is up-to-date and archived correctly. Ensure "state of the art" GxP know-how and future trends in the field of GxP

About the Role

Key Responsibilities:

- Ensure that all aspects of the handling, manufacturing and distribution of biopharmaceutical / pharmaceutical products are in compliance with the Novartis Quality Manual, the effective Quality Agreement that they meet relevant GxP regulatory requirements and are conducted according to local SOPs.
- Prepare, review and check the batch documentation for correctness, completeness and safely

archive the original documents for the prescribed period and plan, conduct and monitor self-Inspection schemes for all sections.

- Monitor actions and corrections accordingly.
- Conduct GxP monitoring on all sections, conduct QA investigation for noncompliance, follow up the corrective actions.
- Archive relative documentations and manage/Approve critical quality issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc.) according to the Quality Agreement and the Novartis Quality Manual.
- Ensure investigations are correctly executed.
- Decide escalation to Senior Management Level and lead Global Quality Assessments and manage filing accordingly as well as ensure that Change requests, are managed according to the Novartis SOPs from receipt, through to the implementation and closure.
- Responsible for assessing quality trends and driving continuous improvement for processes and product quality performance and maintain access to regulatory and Pharmaceutical authorities in respect to up-dated GxP ovide latest know how in the field of GxP and other quality related fields.
- Identify repetitive activities and regulatory areas for which SOPs are required.
- Initiate the introduction of SOPs.
- Plan, initiate and monitor basic GxP-training for all employees in regular intervals.

Essential Requirement:

- Participating in volunteer / community projects.
- Functional Breadth.
- · Collaborating across boundaries.
- Operations Management and Execution.

Skills:

- · Change Control.
- Continuous Learning.
- Dealing With Ambiguity.
- · Guideline.
- Product Release.
- Qa (Quality Assurance).
- Quality Management.
- · Regulation.
- 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

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门 Operations **Business Unit** Quality 地点 Singapore 站点 Mapletree Business City (MBC) Company / Legal Entity SG04 (FCRS = SG004) Novartis Singapore Pte Ltd **Functional Area** Quality Job Type Full time **Employment Type** Regular

Shift Work

No

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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