

Quality Manager

Job ID
REQ-10045946

4月 27, 2025

China

摘要

The Quality Manager responsible for quality oversight of development project in global CMC team. Provide quality assurance expertise, guidance and support to operational activities in development and research organizations to ensure compliance with applicable regulatory requirements and Novartis procedures and quality standards. Manage projects, including Quality Plan initiatives, and processes that support quality objectives to assure their compliance with GxP regulations.

About the Role

Major accountabilities:

- Ensure quality oversight for the assigned development projects with strong quality guidance, scientific and technical expertise. Support TRD CMC team with respect to all quality aspects.
- Manage and support quality aspects of projects and activities, including those related to third parties, analytical instruments, manufacturing equipment, quality plans, training, IT

validations, etc. Review and approve quality deliverables to ensure compliance.

- Review and approval of GMP relevant documents and decision making up to drug substance with authority of Quality Manager. Perform technical release decision of drug substance with the delegation of FvP/RP.
- Review and approval of qualification / validation and release documents of facility, manufacturing equipment, laboratory instruments and IT systems for GMP use.
- Quality incident management including deviation, OOS/OOE and escalation. Assist with root cause investigations and Support the development of corrective and preventative action plans (CAPA), including monitoring status to ensure issues are addressed, completed and documented.
- Change control management to ensure that all the aspects and full impact are appropriately evaluated, addressed and documented.
- Review or Approval of Third Parties and documents related to Third Party Management
- Establish and maintain QA documentation systems such as applicable global standard, SOP ' s, Site Master File.
- Provide support to TRD line functions in GMP related topics as per area of responsibility.

Key performance indicators:

- Clusters Quality System in place and continuously updated, as required risks proactively identified and effectively mitigated -The number and severity issues identified during internal and external audits.
- Demonstrated/recognized leader of specific GxP; early external/industry engagement
-Sufficient financial knowledge (e.g., cost management, budget forecast, etc.) -Role Model of Novartis culture, values and behaviors

Essential Requirements:

- Bachelor (> 5 years ' pharma quality or operations) Masters (> 3 years ' pharma quality or operations).
- Broad knowledge of cGMP, working experience in technical drug development, manufacturing or quality.
- Sound knowledge of current international regulatory regulations, cGxP requirements and best practices, including EU-GMP guidelines.
- Good organizational and decision-making skills. Good and proven ability to analyze and evaluate cGMP compliance.
- Project Management
- Excellent verbal and written communication skills.

Skills:

- Agility.
- Analytical Development.
- Audit Management.
- Auditing.
- Business Partnering.
- Change Control.
- Continuous Learning.

- Health Authorities.
- Influencing Skills.
- Knowledge Of Capa.
- QA (Quality Assurance).
- Quality Management.
- Risk Management.
- Root Cause Analysis (RCA).
- Self Awareness.
- Six Sigma.
- Sop (Standard Operating Procedure).
- Technological Expertise.

Languages :

- Fluent English required (oral & written).

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部门
Development

Business Unit
Innovative Medicines

地点
China

站点

Changshu (Jiangsu Province)

Company / Legal Entity

CN23 (FCRS = CN023) Suzhou Novartis Technical Development Co., Ltd.

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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