Quality Manager

Job ID
REQ-10068201

12月 08, 2025

China

摘要

The Quality Manager is 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.

- 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.
- 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 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:

- In accordance with departmental objectives such as support of projects with agreed quality and delivery dates, passing of internal and external inspections.
- Maintain sound working relationship with internal customers and external partners.
- Meet quality and timelines in all projects.
- Act in accordance with Novartis standards in particular: cGMP, ethical, health safety and environment (HSE), and information security (ISEC)

Minimum 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, analytics 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
Development

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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