NOVARTIS

(Senior) Quality Manager

Job ID
REQ-10079049
Июн. 22, 2026
Китай
Available in: English

Сводка

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). Experience in xRNA filed is preferred.
- 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 communication skills in global environment.

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).

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.
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Дивизион
Development
Business Unit
Development
Место
Китай
Сайт
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

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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