

QC and AS&T Lead

Job ID
REQ-10030198

11月 29, 2024

China

摘要

To provide Quality Control and management expertise for the China RLT project in all quality related matters and to ensure that key aspects of the operational business comply with cGMP and regulatory requirements as well as the key Novartis corporate quality policies.

Role model with the Novartis technical expert framework and cultural aspirations. Might provide on shift support to ensure product quality compliance according to business needs

About the Role

Major accountabilities:

- As per the local project schedule to strictly complete and follow up QC actions/tasks timely. Escalate issue and work with internal and external stakeholders to resolve issue. Complete Ch.P gap assessment in 2025
- Lead and complete QC equipment PQ, analytical method transfers and method validation.

Manage QC utility, standards, solvent, reagents, etc. to keep safety stock in lab and no impact will be caused by lacking or non-conformance. Manage stability sample and complete relevant test as per plan

- Good communication and collaboration with global QC and AS&T experts to guarantee local quality milestones can be achieved.
- Complete method validation protocol and report timely. Initiate local QC procedures (e.g., SOPs, WI, Form, analytical method, etc.)
- On time complete testing for validation samples. Complete lab investigation if any OOX and/or deviation occurred. Support audit and inspection; As the function SME to answer question from auditor and/or inspector without critical findings.
- Function representative to be involved in global and/or local project if any.
- Introduction of new technologies; drives implementation of new requirements.
- Ensure QC activities executed according to cGxP standards
- Lead team and coaching talents. Ensure the consistency between career development processes and the business strategy
- Ensure that associates are qualified for a GMP task prior to independent performance. Monitor overall training compliance for in-scope associates

Essential Requirements:

- 8-10 years professional experience in the field of GMP QC , with Sterility Product Manufacturing in a pharmaceutical industry environment or equivalent
- University degree in Pharmacy, Engineering, Chemistry, Biotechnology or equivalent
- Fluent (oral and written) in English; local language desired
- Current Pharmacopoeia and GxP requirements, relevant official guidelines and regulations (e.g. FDA, EU, ICH, etc.) and TQM with regard to the area of Quality Control and Quality Assurance
- Expertise in GxP operations; Strong analytical background.
- MS Office applications and other standard IT applications supporting Quality activities
- Collaboration; result-oriented. Budget management, Risk Management. Advanced communication skills; motivates colleagues and co-workers. Leadership and change management, objective setting and performance management. Highly structured working style.
- Applied Business Insights, Project Excellence, Stakeholder Engagement, Organizational Savvy

Desirable Requirements:

- Professional experience on analytical test method development/transfer and validation
- Project management, Operations Management and Execution, People Leadership, Collaborating across boundaries, Functional Breadth, Project Management, Financial Management, Industry/ Business Exposure.

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/sites/novartiscom/files/novartis-life-handbook.pdf>

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.

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>. You can follow us via Novartis Recruitment WeChat Official Account and Novartis Recruitment WeChat Video Account.

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>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>

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

Innovative Medicines

地点
China

站点
Haiyan (Zhejiang Province)

Company / Legal Entity
CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

[Apply to Job](#)

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.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.



Job ID
REQ-10030198

QC and AS&T Lead

[Apply to Job](#)

Source URL:

<https://prod1.novartis.com.cn/careers/career-search/job/details/req-10030198-qc-and-ast-lead>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>

2. <https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf>
3. <mailto:diversityandincl.china@novartis.com>
4. <https://talentnetwork.novartis.com/network>
5. <https://www.novartis.com/about/strategy/people-and-culture>
6. <https://talentnetwork.novartis.com/network>
7. <https://www.novartis.com/careers/benefits-rewards>
8. <https://platform.moseeker.com/m/customize/page/novartis?jobnumber=REQ-10030198>
9. <mailto:diversityandincl.china@novartis.com>
10. <https://platform.moseeker.com/m/customize/page/novartis?jobnumber=REQ-10030198>