

Senior QA Operations Specialist, RLT CN

Job ID
REQ-10030206
Nov 17, 2024
Cina

Sommario

About the role:

Responsible to ensure compliance to cGxP standards for products within area of responsibility (during development, transfer and commercialization) and product release.

Provide guidance, support and leadership to teams within area of responsibility. Functionally report to QA Operations Lead

Might run shifts to support product release according to business needs.

About the Role

Key Responsibilities

- Local SOP initiation. Documentation Management and archiving.
- Training management and compliance tracking
- Support validation activities. CAPA management and follow up. Batch Record review
- Collaboration in GxP audits/inspections. Oversight of Quality Operations
- QA Operational Excellence. Complete other tasks be assigned by line manager
- Promote and improve the Safety and Quality cultures, by implementing the necessary systems and actions in line with the evolution of the project
- Ensure overall inspection readiness for area of responsibility.
- Guarantee the effectiveness of the Business Continuity Plan
- Being part of the project crisis management team and depending on skills, expertise and experience can be appointed to one of the NEM roles (Novartis Emergency Management). By delegation of the project Manager may be required to take decisions and take the necessary actions, in particular within the framework of the on-call management system.
- Responsible for participating in initial training and retraining. HSE incidents reporting & action follow-up

Essential Requirements:

- Minimum: 5-8 years' experience in the field of Quality Assurance and
- Sterility Product Manufacturing in a pharmaceutical industry environment or equivalent
- Sufficient experience on audit and inspection preparation and management
- Deeply understanding on cGMP .
- University degree in Pharmacy, Engineering, Chemistry, Biotechnology or equivalent
- Fluent (oral and written) in English; local language desired
- Knowledgeable on GMP Quality Assurance and Manufacturing Process/Product Expertise. Expertise in GxP operations
- Audit Management; Health Authorities; Technical Launch and Transfer. Risk Management. Collaboration;

result-oriented. Advanced communication skills;

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/novartis_com/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>

Divisione

Operations

Business Unit

Innovative Medicines

Posizione

Cina

Sito

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-10030206

Senior QA Operations Specialist, RLT CN

[Apply to Job](#)

Source URL: <https://prod1.adacap.com/careers/career-search/job/details/req-10030206-senior-qa-operations-specialist-rlt-cn>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. https://www.novartis.com/sites/novartis_com/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://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Haiyan-Zhejiang-Province/Senior-QA-Operations-Specialist--RLT-CN_REQ-10030206-1
9. <mailto:diversityandincl.china@novartis.com>
10. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Haiyan-Zhejiang-Province/Senior-QA-Operations-Specialist--RLT-CN_REQ-10030206-1

