

QA Compliance Senior Specialist

Job ID
REQ-10033876
Dec 17, 2024
China

Summary

- GxP

About the Role

Major Accountabilities

1 Ensure and support the quality system and related tools been setup, carried out and properly maintained, to meet with the regulatory changes and business development.

2 Track China GxP Regulatory intelligence, lead regulation gap assessment and coordinate the regulation implementation with relevant functions.

GxP

3 Responsible for Novartis vendor management and ensure control of third parties by regular inspections and follow ups. Participate in global GMP/GSP audits at China CPO operations and supervision of follow-up action plans.

CAPA GMP/GSP

4 Ensure that appropriate, accurate & up-to-date signed quality agreements with third parties are in place for all GMP/GSP activities.

GMP/GSP

5 Responsible for GOP implementation at local level and documentation management, cooperate with functions/ESOPS manager for SOP/WP lifecycle management.

GOP /ESOPS

6 Responsible for training management such as training matrix, ensure GxP personnel training comply with Novartis and local regulation requirements.

GxP

7 Participate e-system / digital tools roll out and upgradation, and ensure compliance to Novartis and local regulation requirements at GxP area.

/ GxP

8 Manage QM/QD implementation that ensures continuous compliance with Novartis global Quality Manual and local regulatory requirements.

/

9 Lead/support global or local quality project.

10 Provide effective compliance supports and services to other functions.

Key Performance Indicators

Ensure NCQ KQIs of the GMP/GSP part.

GMP/GSP NCQ KQI

CAPA follow-up, no overdue occurs on the Inspection, Audit, Q-plan and Country Organization Risk Assessment related CAPA plan.

CAPA

Vendor management, up-to-date signed QAA with third parties.

Ensure China GxP Regulatory intelligence and compliance.

GxP

Ensures Novartis global Quality Manual and GOP implementation.

Work Experience

: Bachelor degree above, pharmaceutical major relevant, license pharmacist is preferred

: Effective oral and written abilities in English.

:

At least 3 years working experiences in QA function or GMP/GSP related experiences in pharmaceutical joint venture.

3 GMP/GSP QA

Be familiar with the law for pharmaceutical manufacturing and in-depth understanding of current GMP/GSP.

GMP/GSP

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>

Division

Operations

Business Unit

Innovative Medicines

Location

China

Site

Shanghai (Shanghai)

Company / Legal Entity

CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd

Functional Area

Quality

Job Type

Full time

Employment Type

Shift Work

No

[Apply to Job](#)

diversityandincl.china@novartis.com

Job ID

REQ-10033876

QA Compliance Senior Specialist

Source URL: <https://prod1.id.novartis.com/careers/career-search/job/details/req-10033876-qa-compliance-senior-specialist-zh-cn>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. <https://www.novartis.com/careers/benefits-rewards>
4. https://novartis.wd3.myworkdayjobs.com/zh-CN/Novartis_Careers/job/Shanghai-Shanghai/QA-Compliance-Senior-Specialist_REQ-10033876
5. <mailto:diversityandincl.china@novartis.com>
6. https://novartis.wd3.myworkdayjobs.com/zh-CN/Novartis_Careers/job/Shanghai-Shanghai/QA-Compliance-Senior-Specialist_REQ-10033876