QA Compliance Senior Specialist

Job ID
REQ-10033876
Dic 17, 2024
China

Resumen

- 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.

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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

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