

## QA Compliance Senior Specialist

Job ID  
REQ-10033876

12月 17, 2024

China

### 摘要

在责任范围内管理质量方面和项目。  
确保和支持全面的 GxP 符合性和符合诺华质量管理体系

### 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.

在快速更新的法规环境和业务迅速发展变革的环境下，确保和支持质量体系及相关管理工具的建立，执行和相应的维护。

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

跟踪中国GxP法规更新,负责法规差距评估,并协调相关部门实施法规要求。

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.

负责诺华供应商管理,确保第三方定期审计和CAPA的及时跟踪。参与总部GMP/GSP的审计并跟踪后续整改措施的完成。

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

确保适当、及时、准确地与供应商签署质量协议来规范其GMP/GSP操作。

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

负责总部GOP在本地的实施,文档的管理,与各部门/ESOPS管理员协作确保流程文件的制定、批准、生效、保存等。

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

负责培训体系例如管理培训矩阵,确保GxP 人员培训符合诺华和当地法规的要求。

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

参与电子系统/数据工具的实施和升级,确保GxP相关的计算机系统符合诺华和当地法规的要求。

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

管理质量手册/质量指导的实施,确保持续的符合诺华总部质量手册和本地法规的要求。

9 Lead/support global or local quality project.

负责或支持总部或本地质量部项目。

10 Provide effective compliance supports and services to other functions.

提供对其他部门有效的合规支持和服务。

Key Performance Indicators

Ensure NCQ KQIs of the GMP/GSP part.

确保GMP/GSP 部分的 NCQ KQI。

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

确保在检查, 审计, 质量计划和风险评估中的CAPA及时追踪, 没有超期。

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

供应商管理, 及时更新与第三方的质量协议。

Ensure China GxP Regulatory intelligence and compliance.

确保中国GxP法规更新及时实施和合规。

Ensures Novartis global Quality Manual and GOP implementation.

确保持续的符合诺华总部质量手册和管理流程的实施。

## Work Experience

教育: Bachelor degree above, pharmaceutical major relevant, license pharmacist is preferred  
医药相关专业本科以上学历, 执业药师优先

语言: Effective oral and written abilities in English. 流畅的英文口语和书写能力

## 经验:

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

至少3年制药领域GMP/GSP QA相关工作经验。

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

熟悉药品生产相关法律法规, 深刻理解现行GMP/GSP。

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部门

Operations

Business Unit

Innovative Medicines

地点

China

站点

Shanghai (Shanghai)

Company / Legal Entity

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

Functional Area

Quality

Job Type

Full time

Employment Type

正式

Shift Work

No

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