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系统

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。

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
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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诺华 承 诺 与残障人士共事并 为 他 们 提供合理的便利 设 施。如果您由于健康状况或残障 在招聘 过程的任何 环 节 需要合理便利 设 施 或者 为 了履行 职 位的基本 职 能 请发 送 电 子 邮 件至 diversityandincl.china@novartis.com 告知您的需求和 联 系方式，并在 邮 件中附上您的 职 位申 请编号。

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