NOVARTIS

QA Manager

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Китай

Сводка

Responsible for cooperative setting up and maintaining Quality System to ensure Novartis Quality Manual, local regulatory and GMP/GDP/GSP compliance requirements continually be implemented in operational functions, ensure that local operation procedures and practice remain current in line with local regulatory, and Novartis QM requirements; ensure improvements be in place timely and properly.

负责协同建立和维护质量体系，确保诺华质量手册、当地法规和GMP、GDP、GSP合规要求在运营职能部门持续实施，确保当地操作程序和实践符合当地法规和诺华质量管理要求；确保持续改进措施及时和适当地贯彻执行。

About the Role

主要职责 ：

- Ensure compliance with global standards and local regulations.
- 确保遵守全球标准和当地法规。
- Be responsible for maintaining and improving the Quality Management System (QMS) , ensuring necessary licenses are maintained.
- 负责维护和改进质量管理体系（QMS）。
- Accountable for the quality of the products marketed and ensuring necessary licenses are maintained.
- 对营销产品的质量负责，确保持有必要的许可证。
- Responsible DMAH implementation and oversight. Responsible for product annual report.
- 负责 DMAH 要求的实施和监督。负责产品年度报告。
- Supply Chain & Logistics: Oversee storage in qualified warehouses, incoming goods checks and transportation.
- 供应链与物流：监督合格仓库的储存、进货检查和运输。
- Health Authority Liaison: Serve as the primary point of contact for Health Authorities (e.g., ZJMPA) for GSP matters, including inspections
- 药监部门联络员：担任药监部门（如 ZJMPA）有关 GSP 事宜（包括检查）的主要联络人。
- Complaint Handling: Ensure the correct processing of Product Complaints and counterfeit cases.
- 投诉处理：确保正确处理产品投诉和假冒案件。
- Support managing quality issues, including product recall and mock recall, drug shortages, and quality information analysis and management.
- 支持管理质量问题，包括产品召回和模拟召回、药品短缺和质量信息的分析管理。
- Assist in the reporting and monitoring of adverse events of pharmaceutical products.
- 协助完成经营药品的不良反应的报告和监测工作。
- Organize quality education and training.
- 组织开展质量管理教育和培训。
- Product Release & Distribution: responsible for product final release, management of returned goods.
- 负责产品的最终释放和退货管理。
- Responsible for distributor (transportation supplier) management, including qualification/approval of distributor, QAA execution, and day-to-day business coordination and support. Organize the survey, review and evaluation of the quality management system and service of vendors, wholesalers and distributors if required.
- 负责运输商的管理，包括运输商的确认、QAA签订、日常业务协调支持等。必要时组织对供货单位、购货单位，以及运输商质量管理体系和服务质量的考察、审核和评价。
- Provide quality support of BD&L case:
- - Set up and optimize the quality assurance (QA) system for business development projects and lead the quality control of the whole project life cycle, including due diligence support, partner selection, and coordination of writing and signing of quality assurance agreements (QAA) with partners.
- - 支持BD&L业务：搭建并优化适配业务拓展项目的质量保证（QA）体系，主导项目全生命周期质量管控，涵盖尽职调查支持、合作伙伴筛选，以及与合作伙伴质量保证协议（QAA）的撰写与签署协调。
- - Serve as the quality interface window for business partners, manage complaints, deviations, changes and other quality matters in a unified manner to ensure continuous and stable market supply.
- - 作为业务合作伙伴的质量对接窗口，统一管理投诉、偏差、变更等质量事项，确保市场供应持续稳定。
- - Organize and implement quality audits to partners, identify quality and compliance risks, develop and track corrective and preventive actions (CAPAs) to ensure continuous improvement and GxP compliance.
- - 组织并实施合作伙伴质量审计与体系评估，识别质量与合规风险，制定并跟踪纠正预防措施（CAPA），确保持续改进与GxP合规。
- Assist the quality responsible person to establish and maintain the quality management system to ensure compliance with local laws, regulations and Novartis global policies.
- 协助质量负责人共同建立并维护质量管理体系，确保其符合本地法律，法规及诺华总部政策。

关键绩效指标：

- All applicable Quality Modules from the Novartis Quality Manual are implemented and regulatory controls are in place at relevant process steps.
- 实施诺华质量手册中所有适用的质量模块并在相应流程步骤中进行管控。
- Relevant Key Quality Indicators are defined and implemented by regular management review to monitor compliance and quality performance.
- 明确落实相关质量关键指标并定期监管合规及表现。
- Assist in ensuring success in internal audit and HA inspection.
- 协助确保成功的内部审计及药监部门检查接待。
- Refrain from causing stock shortages because of inefficient quality inspection practices.
- 不因低效质量验收的原因而导致缺货。

- Ensure proper management of GxP training.
- 确保 GxP 培训得到合适管理。
- Ensure proper management of transportation suppliers and partners.
- 确保运输商和合作伙伴被合适地监管。

专业及综合能力要求：

- Bachelor’s degree and above in Pharmacy or related fields, compliant with local requirements for "Authorized Persons". Licensed pharmacist.
- 药学相关专业、本科或以上学历，符合当地对 "授权人员 "的要求。具有执业药师资格。
- Highly fluent in English (Written & Spoken)
- 英语熟练（书面和口头）。
- Minimum of 5 years of professional experience in the pharmaceutical industry within a GMP/GSP environment, familiar with local and international cGMP/GDP.
- 在制药行业的 GMP/GSP 环境中至少有 5 年的专业经验，熟悉本地和国际 cGMP/GDP。
- Leadership Skills: ability coordinate across function and deliver impact.
- 领导技能：有能力协调各职能部门并产生影响。
- Problem-Solving: Creative and independent ability to handle complex tasks and solve problems under pressure.
- 解决问题：具有在压力下处理复杂任务和解决问题的创新和独立能力。
- Communication & Negotiation: Fluent verbal and written communication skills in both English and the local language, with strong negotiation skills.
- 沟通与谈判：流利的英语和当地语言的口头和书面交流技能，以及较强的谈判技能。
- Crisis Management: Ability to proactively manage conflicts, challenges situations.
- 危机管理：主动处理冲突和挑战的能力。
- Stakeholder Engagement: Experience in interacting with health authorities and ability of stakeholder management.
- 与内外部关联人员的沟通能力：与药品监管部门互动的经验以及与相关人员的沟通的能力。

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: Learn about all the ways we’ll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Operations
Business Unit
Quality
Место
Китай
Сайт
Shanghai (Shanghai)
Company / Legal Entity
CN27 (FCRS = CN027) 诺华医药科技（浙江）有限公司
Functional Area
Quality
Job Type
Full time
Employment Type
正式
Shift Work
No

无障碍及便利 设 施

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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