NOVARTIS

GSP QP Manager

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Китай

Сводка

- Ensure the company's pharmaceutical distribution activities remain compliant with China GSP regulations and Novartis quality standards and the effective implementation of product release.
- Support the quality system management, Pharmaceutical Trade License maintenance, and third-party logistics oversight, while enabling business continuity and the successful delivery of strategic initiatives.

About the Role

Major Accountabilities:

- Review documentation and information related to pharmaceutical products and make distribution release or rejection decisions, ensuring compliance and that all related records are accurate, complete, reliable, and traceable. Assess and determine the disposition of nonconforming products, returned products, and other products with quality-related issues.
- Responsible for the oversight of third-party warehousing and logistics service providers, and for supporting Health Authority market sampling activities.
- Manage or coordinate Pharmaceutical Trade License renewals, amendments, and maintain effective communication with Health Authorities to ensure compliance with regulatory requirements.
- Review the legitimacy of suppliers, procured products, and the qualifications of supplier sales representatives, and ensure ongoing management based on changes in review outcomes.
- Review documentation for initial suppliers and initial products, coordinate the approval process, and ensure procurement is conducted only after approval by the Quality Responsible Person.
- Conduct assessments and evaluations of pharmaceutical suppliers' quality management systems and service quality, perform periodic quality reviews of procurement activities, establish and maintain pharmaceutical quality review records and supplier quality files, and ensure their effective maintenance and dynamic management.
- Collect and manage quality information and establish pharmaceutical quality records.
- Confirm non-conforming products and oversight the handling and disposition process of non-conforming pharmaceuticals.
- Manage product quality inquiries and coordinate the investigation, handling, and reporting of quality incidents.
- Develop the annual self-inspection plan, organize and lead the self-inspection and risk assessments, and oversight the definition, implementation, and timely closure of CAPAs.
- Fulfill quality responsibilities for Computerized Systems，including: provide guidance on the configuration and implementation of quality control functions within computerized systems; review and approve user access rights for computerized systems, and periodically review and verify SAP system functional access permissions; ensure that all personnel operate computerized systems in compliance with established procedures and requirements; review and approve quality master data, authorize its activation, and ensure appropriate data locking and control; review requests for business data changes and approve modifications only when they comply with applicable requirements and approved procedures; manage and resolve quality-related issues associated with computerized systems that may impact pharmaceutical products.
- Prepare the annual validation plan and summary and review validation protocols and reports.
- Review and approve the annual GSP training plan and oversight its implementation.
- Ensure that relevant departments and personnel comply with pharmaceutical regulations and Good Supply Practice (GSP) requirements.
- Guide and oversight quality management activities throughout pharmaceutical procurement, storage, maintenance, sales, returns, and transportation processes.
- Report counterfeit and substandard pharmaceuticals and support adverse drug reaction (ADR) reporting activities.
- Support new product launches, new projects, and change management activities in line with business development needs.
- Maintain effective cross-functional collaboration with Supply Chain, Commercial, IT, Regulatory Affairs (RA), Patient Safety, P&O, and external partners to proactively resolve quality issues, mitigate risks, and ensure business continuity.
- Perform other quality management responsibilities as assigned by the company.

Key performance indicators:

- 100% compliant and timely product distribution release; zero regulatory issues resulting from quality review or release decision errors.
- Zero compliance risks resulting from inadequate oversight of third-party warehousing and logistics service providers.

Education:

Bachelor’s degree or above in Pharmacy, Medicine, Biology, Chemistry. Licensed Pharmacist certification is required.

Language:

Fluent in English, with strong verbal and written communication skills.

Working Experience:

At least 3 years of experience in pharmaceutical quality management within pharmaceutical GSP field. Familiar with the China Drug Administration Law, Good Supply Practice (GSP) requirements, and other applicable pharmaceutical regulations.

Professional and Competency Requirements:

Demonstrates a high level of diligence and attention to detail, with strong compliance awareness and sound quality judgment. Possesses strong capabilities in risk assessment, cross-functional collaboration, communication, execution, and time management. Able to independently identify, assess, and resolve quality issues arising throughout pharmaceutical distribution operations while ensuring regulatory compliance and business continuity.

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)

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Quality
Место
Китай
Сайт
Beijing (Beijing)
Company / Legal Entity
CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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