

Sr. QA Operations Specialist

Job ID
REQ-10079050
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Китай

Сводка

This role provides quality oversight for daily operations, reviews documentation, supports investigations, manages deviations and CAPAs, ensuring compliance with internal procedures, regulatory requirements, cGxP and industry standards ; drives continuous improvement initiatives across quality systems.
该职位负责对日常运营活动进行质量监督，审核相关文件，支持调查工作，管理偏差和纠正预防措施，确保各项工作符合公司内部程序、法规要求、cGxP及行业标准；推动质量体系的持续改进。

The position requires strong knowledge of QA operations, documentation practices, compliance, and cross-functional coordination with Production, Quality Control, Regulatory Affairs, Supply Chain, and other relevant departments.

该职位要求具备扎实的质量保证运营、文件管理、合规相关知识，并能够与生产、质量控制、注册法规、供应链及其他相关部门进行有效的跨部门协作。

About the Role

Major Accountabilities
主要职责

- Provide QA oversight for routine operational activities to ensure compliance with approved procedures and regulatory requirements.
对日常运营活动提供质量保证监督，确保其符合已批准的流程和法规要求。
- Review master batch document, operational documents, logbooks, forms, and other GMP-related documentation.
审核主批记录、运营相关文件、日志、表格及其他与GMP相关的文件。
- Support the management of deviations, non-conformances, investigations, root cause analysis, CAPA, and change controls.
支持偏差、不符合项、调查、根本原因分析、纠正预防措施及变更控制的管理。
- Ensure timely review, closure, and follow-up of quality events and quality system records.
确保质量事件和质量体系记录得到及时审核、关闭和跟进。
- Participate in internal audits, external audits, regulatory inspections, and customer audits as required.
根据需要参与内部审计、外部审计、法规检查及客户审计。
- Monitor compliance with Good Manufacturing Practices, Good Documentation Practices, and company quality standards.
监督良好生产规范、良好文件规范及公司质量标准的符合性。
- Support the development, review, and revision of SOPs, work instructions, forms, and other GMP document.
支持标准操作规程、工作指导书、表格及其他GMP文件的制定、审核和修订。
- Provide QA support for product release activities, including documentation review and compliance checks.
为产品放行活动提供质量保证支持，包括文件审核和合规性检查。
- Collaborate with cross-functional teams to resolve quality issues and implement process improvements.
与跨部门团队合作，解决质量问题并实施流程改进。
- Track and report quality metrics, trends, and key performance indicators.
跟踪并汇报质量指标、趋势及关键绩效指标。
- Support training activities related to quality systems, GMP compliance, documentation practices, and procedural updates.
支持与质量体系、GMP合规、文件规范及程序更新相关的培训活动。
- Ensure that quality risks are identified, assessed, escalated, and mitigated appropriately.
确保质量风险得到识别、评估、升级和适当控制。
- Assist in preparing quality reports, management review inputs, and audit readiness documentation.
协助准备质量报告、管理评审资料及审计准备文件。
- Mentor junior QA team members and provide guidance on quality processes and compliance expectations.
指导初级质量保证团队成员，并就质量流程和合规要求提供支持。
- Promote a culture of quality, compliance, and continuous improvement across the organization.
在公司内部推动质量、合规和持续改进文化。

Key Performance Indicators
关键绩效指标

- Execute product-related quality activities in a timely manner and in compliance with cGxP and registration requirements.

及时开展与产品相关的质量活动，并确保符合cGxP及注册要求。

- Demonstrate positive performance trends across key quality management process indicators.

在关键质量管理流程指标方面展现出积极的绩效改善趋势。

- Contribute effectively to continuous improvement projects that support quality and operational performance.

有效参与支持质量与运营绩效提升的持续改进项目

Education and Work Experience

教育背景和工作经历

- Bachelor or master's degree in Pharmacy, Chemistry, Biology, Microbiology, Life Sciences, or a related discipline.
药学、化学、生物学、微生物学、生命科学或相关专业本科及以上学历。
- Minimum of **3-5 years of experience** in Quality Assurance, Quality Operations, pharmaceutical manufacturing operations or a related quality function.
至少 **3-5年** 质量保证、质量运营、制药生产运营或相关质量职能工作经验。
- Experience in a regulated industry such as pharmaceuticals, biotechnology, medical devices, food manufacturing, or healthcare products.
具备制药、生物技术、医疗器械、食品制造或健康产品等受监管行业经验。
- Strong understanding of GMP, GDP, quality systems, deviations, CAPA, change control, and audit processes.
熟悉GMP、GDP、质量体系、偏差、CAPA、变更控制及审计流程。
- Experience reviewing batch records, SOPs, validation /qualification documents, and operational quality documentation.
具备审核批记录、标准操作规程、验证/确认文件及运营质量文件的经验。

Language

语言能力

- Good (oral and written) in English; fluent in local language (oral and written)

良好的英语水平（口头和书面）；流利的当地语言（口头和书面）

Key Skills and Competency

关键技能与能力

- Strong attention to details and commitment to compliance.
注重细节，并高度重视合规要求。
- Excellent written and verbal communication skills.
具备优秀的书面和口头沟通能力。
- Strong analytical, problem-solving and decision-making abilities.
具备较强的分析、问题解决和决策能力。
- Ability to manage multiple priorities and meet deadlines.
能够同时管理多项任务并按时完成工作。
- Effective collaboration with cross-functional teams.
能够与跨部门团队进行高效协作。
- Ability to work independently with minimal supervision.
能够在较少监督下独立开展工作。
- Strong leadership and mentoring skills.
具备较强的领导力和指导能力。
- High level of integrity, accountability, and professionalism.
具备高度诚信、责任感和职业素养。

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

Changping County (Beijing)

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

无障碍及便利设施

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