NOVARTIS

QA Operations Specialist

Job ID
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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

教育背景和工作经验

- 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

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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