Sr GMP Auditor

Job ID
REQ-10047906

5月 05, 2025

Brazil

摘要

-Manage cost effective GxP Compliance and/or Audit activities, operations and systems to ensure compliance of business areas with the Novartis Quality Manual and Policies and all relevant GxP, legal and regulatory requirements, and through internal audits, KPIs (Key Performance Indicators) and KQIs (Key Quality Indicators) -Performs preparation and management of external and corporate audits and Health Authority inspections.

About the Role

Major accountabilities:

- **Audit Planning:** Develop and implement audit plans and schedules for GMP compliance.
- **Conduct Audits:** Perform detailed audits of manufacturing processes, facilities, and documentation to ensure adherence to GMP standards.
- **Compliance Verification:** Verify that all operations comply with regulatory requirements and

industry best practices.
- **Report Findings:** Document audit findings and prepare comprehensive reports outlining observations, non-compliances, and recommendations.
- **Corrective Actions:** Collaborate with departments to develop and implement corrective actions for identified issues.
- **Training:** Provide training and guidance to staff on GMP requirements and best practices.
- **Continuous Improvement:** Identify opportunities for process improvements and contribute to the enhancement of quality systems.
- **Regulatory Updates:** Stay informed about changes in GMP regulations and ensure the organization remains compliant.
- **Risk Management:** Assess risks associated with manufacturing processes and recommend mitigation strategies.

Key performance indicators:

- Successful support of projects with agreed quality and delivery dates, passing of internal and external inspections.
- Meet quality and timelines for all projects -Act in accordance with Novartis standards.
- The number and severity of cGMP issues identified during internal and external audits -Year-end figures within budget; Successful coordination of departmental operational activities
- **Compliance Rate:** Percentage of audited processes and facilities found to be in compliance with GMP standards.
- **Training Effectiveness:** Evaluation of the effectiveness of training sessions conducted, often measured through post-training assessments and feedback.
- **Repeat Findings Rate:** Frequency of recurring issues identified in subsequent audits, indicating the effectiveness of corrective actions.
- **Stakeholder Satisfaction:** Feedback from audited departments and stakeholders regarding the audit process and outcomes.

Minimum Requirements:
Work Experience:

- **Education:** Bachelor's degree in Pharmacy, Chemistry, Biology, or a related field.
- **Experience:** Extensive 10 + y experience in GMP auditing, quality assurance, or regulatory affairs within the pharmaceutical industry.
- **Skills:** Strong analytical skills, attention to detail, excellent communication and interpersonal skills, and proficiency in audit management software.
- **Certifications:** Certification in GMP auditing or quality management is preferred.

Preferred Qualifications:

- **Advanced Degree:** Master's degree in a related field.
- **Technical Expertise:** In-depth knowledge of GMP regulations and guidelines, and experience with electronic quality management systems (EQMS).

Languages :

- English, Spanish, Portuguese

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部门
Operations

Business Unit
Innovative Medicines

地点
Brazil

站点
Santo Amaro

Company / Legal Entity
BR03 (FCRS = BR003) NOVARTIS BIOCIENCIAS S.A

Alternative Location 1
INSURGENTES, Mexico

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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