QA Compliance Specialist

Job ID
REQ-10058060

7月 23, 2025

Spain

摘要

The Compliance specialist is responsible to collaborate with relevant manager for maintaining and developing the quality systems strategy, policies, processes, standards and procedures to ensure the site complies with regulatory and GMP compliance requirements as described by authorities and by Novartis/Adacap guidelines and quality manual.

The function supports the manager to guarantee that global procedures are implemented in the site ' s quality systems and challenges the system for further improvement. The function supports in the site ' s inspection readiness and is a key contributor of the inspection management program.

About the Role

Major accountabilities:

- Collaborates to ensure that the site ' s quality system is maintained compliant to regulatory and

GMP compliance requirements.

- Collaborates in the management of the site ' s quality systems documentation and reviews, defines updates and approves (when agreed with the quality management) site specific quality systems documents.
- Provides oversight for the implementation of Quality Systems and Regulatory Compliance including management of Non conformances, CAPAs, Effectiveness Checks, Change Controls, Training, Inspections and Audit readiness, Technical complaints, Risk Assessments and remediation, Annual Product Quality review, self-assessments, KPIs and Quality Management
  Review.
- Support the manager in the design and oversight of strategic site quality system and works in collaboration with site functions to define written procedures including but not limited to monitor and control of the manufacturing environment, training, document control/record retention, deviations/CAPA investigations, and monitoring compliance with all requirements of good
  manufacturing practice.
- Support the quality management to develop and deliver a robust overall quality system, strategy, and ultimate plan resulting in a fully compliant quality system infrastructure with respect to procedures and processes.
- Provides oversight for audit and inspection management, inspection strategies, preparation, interactions and responses.
- Support the quality team in the health authority inspection preparation and ensures key support during MOH and Novartis global audits.
- Develop Health Authority communications, including written correspondence, responses to inspection observations, presentations and verbal communication
- Works with quality and compliance team to ensure robust quality systems are implemented and
  sustained including, deviation/CAPA Management: Ensures all deviations from established procedures are appropriately documented and investigated to determine and fix root cause.
- Support escalation of Quality/cGMP issues and deficiencies to the Site QA Head and support global escalation process if needed. Support associates within the Novartis network incase of Health Authority Notifications (s.a. FAR, Rapid alert, recalls)

Minimum Requirements:

- Education: Bachelor ´ s Degree in Pharmacy or MSc in Pharmaceutical Industry.
- 2+ years of experience in a GxP (Bio)pharmaceutical or API manufacturing operations up of which 1+ years of experience in a Quality Assurance role.
- Excellent communication skills
- Fluent English and Spanish, written and spoken.

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部门
Operations

Business Unit
Innovative Medicines

地点
Spain

站点
Zaragoza

Company / Legal Entity
ES45 (FCRS = ES045) AAA Ib é rica S.L.U.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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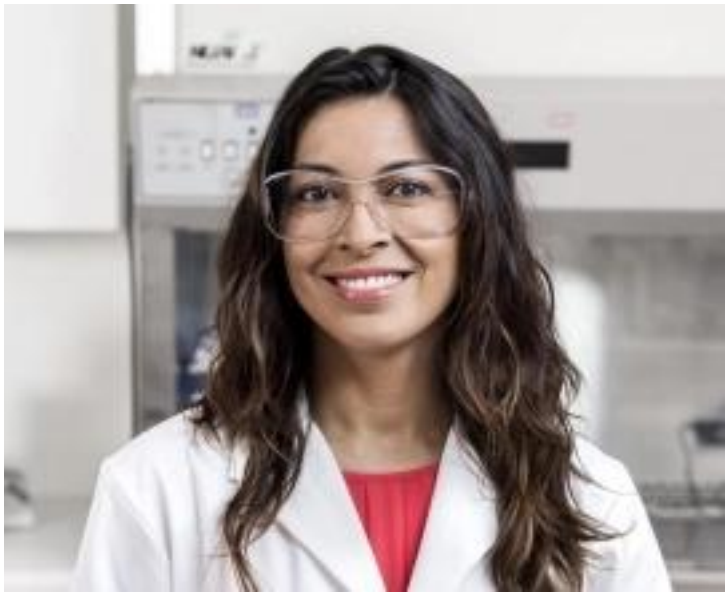

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