Deviations Specialist

Job ID
REQ-10056506

6月 30, 2025

Mexico

摘要

The Deviations Specialist/ QA Investigator is responsible for managing and executing investigations of deviations and non-conformities within manufacturing and quality control environments. This role ensures root causes are identified, corrective and preventive actions (CAPAs) are implemented effectively, and documentation complies with cGMP and Novartis standards.

About the Role

Key Responsibilities:

- Lead and document investigations related to deviations.
- Perform root cause analysis using tools such as 5 Whys, Fishbone, FMEA, etc.
- Collaborate with cross-functional teams (Production, QC, QA, RA, Supply Chain, Engineering, etc.) and international teams (e.g., Argentina, Chile, U.S.) to gather data, perform root cause analysis and drive timely resolution of investigations.

- Ensure CAPAs are defined, implemented, and verified for effectiveness.
- Maintain investigation records in compliance with internal procedures and regulatory expectations.
- Establish and monitor quality KPIs.
- Provide guidance to Business Partners in the activities related to Deviation process to stablish improvements.
- Act as key user for the deviations system, managing access and troubleshooting.
- Support audits/inspections with documentation and participation in discussions.
- Identify trends and recurring issues to support continuous improvement initiatives.
- Contribute to the development and revision of SOPs related to deviation and CAPA management.
- Foster digitalization and the use of artificial intelligence (AI) within a global framework to optimize and streamline processes.
- Support service implementation and transitions (knowledge transfer, go-live, hyper-care).

Specific skills and qualifications:

- Bachelor ' s degree in pharmacy, Chemistry, Biology, or related scientific discipline.
- Minimum 4 years in pharmaceutical QA (preferably in deviation/CAPA management, GMP, regulatory compliance), local/international Health Regulations and Project management.
- Strong knowledge of cGMP, ICH, and regulatory standards.
- Experience with electronic quality systems (e.g., 1QEM, SAP-QM).
- Excellent analytical, communication, and documentation skills.
- Skilled in cross-functional collaboration and process optimization.
- Familiar with business intelligence, design thinking, agile methodologies, and data management.
- Digital skill
- High responsiveness and customer satisfaction.
- English proficiency and Portuguese (desirable).

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部门
Operations

Business Unit
Innovative Medicines

地点
Mexico

站点
INSURGENTES

Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmac é utica S.A. de C.V.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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