NOVARTIS

Deviations Specialist

Job ID
REQ-10056506
Jun 30, 2025
Mexico

Summary

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).

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

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Division
Operations
Business Unit
Innovative Medicines
Location
Mexico
Site
INSURGENTES
Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmacéutica S.A. de C.V.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Ajustes de accesibilidad

Novartis tiene el compromiso de trabajar y proporcionar adaptaciones razonables para personas con discapacidad. Si, debido a una condición médica o discapacidad, necesita una adaptación razonable para cualquier parte del proceso de contratación, o para des empeñar las funciones esenciales de un puesto, envíe un correo electrónico a tas.mexico@novartis.com y permítanos conocer la naturaleza de su solicitud y su información de contacto. Incluya el número de posición en su mensaje.

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