

QA Deviations Specialist

Job ID
REQ-10065740

10月 29, 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

#hybridCDMX

Major accountabilities:

- Oversight of all production and testing activities, ensures compliance with cGxP, incl. data integrity and eCompliance -Support exception investigations -Review and approval of production, QC, and AS and T records -MBR review -Support OpEx improvement projects

Qualified Person - Executes batch release in compliance with registration -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

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 establish 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).

Accessibility and Accommodation:

Novartis is committed to work with and provide reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to tas.mexico@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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 desempeñar 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.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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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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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