Investigation specialist for lab

Job ID
REQ-10068442

12月 08, 2025

Mexico

摘要

The primary responsibility of the Quality Specialist is to manage the day-to-day processes for Deviations including receiving, logging, investigating, and trending of product quality related deviations, liaising with internal manufacturing/Third Party sites, identification, and reporting of high-profile deviation events. Additional responsibilities include and are not limited to attending assigned processes described in present job description, training of employees, compiling, analyzing, and reporting of metrics and strategies that will continuously improve the processes and business partner agreed expectations and outline course of actions as a result.

About the Role

#LIONSITE #NAUCALPAN

Major accountabilities:

- Responsible to open, manage and conduct or follow up (as applicable) the investigation report for closure of deviations in accordance with company and regulatory requirements.
- Responsible for smooth handling of Deviations with appropriate project management skills.
- Open and ensure progression of relevant child records (action, CAPA, effectiveness check, etc) as required.
- Review and evaluate compliance of actions, CAPAs and Effectiveness Check records for approval or rejection when corresponds as per delegation of activities from business partners.
- QA Approver when applicable.
- Act as contact point for Business Partners to follow up the investigations opened in IT system.
- Responsible to comply with timeliness in accordance with global SOP ´ s, and document needed extensions in applicable IT system with appropriate justification.
- Responsible to run queries in the appropriate system and communicate about recurrence in all deviations under associate ' s responsibility.
- Escalate service related GxP and non-GxP issues to appropriate level to ensure timely investigation and compliance with local and global operating procedures.
- Responsible for scheduling meetings to communicate the progress of the process to report deliverable status and continuously acquire process knowledge to determine and assign follow-up action items, if required.
- Responsible to stablish and maintain the KPI ´ s within the quality standards.
- Provide guidance to Business Partners in the activities related to Deviation process to stablish improvements.

1QEM system key user

- Provide support to users in IT system platform when required.
- Be contact point for system troubleshooting to support specific topics.
- Raise IT tickets for technical issues, registration/deregistration of users from platform.

Minimum requirements :

- Knowledge: Quality Systems; Continuous Improvement; Good Manufacturing Practices; local/international Health Regulations; Project Management.

- Skills: Strives for simplicity and clarity; Digital technology Savvy; Continuous Learning; Solution oriented behavior; Self organization; Stakeholder Engagement; Organizational Savvy; Effective communication; Breakthrough analysis; Agile Mindset; Agile Teams.

Education:

Bachelor ' s degree in chemistry, pharmaceutical or life science

Languages:

English, Spanish, Portuguese (desirable), and French (desirable)

Experiences:

At least 3 years of experience into pharmaceutical industry.

Commitment to Diversity and Inclusion

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

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 condici ó n m é dica o discapacidad, necesita una adaptaci ó n razonable para cualquier parte del proceso de contrataci ó n, o para desempe ñ ar las funciones esenciales de un puesto, env í e un correo electr ó nico a tas.mexico@novartis.com y perm í tanos conocer la naturaleza de su solicitud y su informaci ó n de contacto. Incluya el n ú mero de posici ó n en su mensaje.

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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

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门

Operations

Business Unit
Quality

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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