NOVARTIS

Director GxP/Quality Incident Management

Job ID
REQ-10068213

12月 09, 2025

Spain

摘要

The Director of GxP Quality Incident Management is an important position responsible for managing assigned escalated GxP and Quality incidents in an end-to-end process on global level, initiating GxP/Quality incident prevention measures and maintaining (incl continuous improvement) of defined incident management related processes within regulated environments on global level. GxP (Good Practices) guidelines are critical for ensuring product quality, safety, and regulatory compliance in the pharmaceutical / life sciences sector. The Director ensures and oversees that assigned quality incidents are managed effectively, root causes are identified, lessons learned are issued, and corrective and preventive actions (CAPAs) are developed to maintain the highest standards of compliance and patient safety.

The Director of GxP Quality Incident Management is essential for maintaining regulatory compliance, safeguarding patient safety, and ensuring the continued success of quality operations within the organization. This role requires a blend of technical expertise, leadership skills, and a proactive approach to quality and risk management as well as to continuous improvement.

About the Role

Deadline for applications: 31st of December 2025.

Major accountabilities:

- Incident Management and Oversight: Manage and oversee the intake, triage, investigation, documentation, and resolution of GxP and quality-related incidents in an end-to-end process, including resulting from deviations, regulatory and/or GxP non-conformances, and other quality events.
- Processes: Develop, maintain and implement assigned GxP/Quality incident management processes that align with organizational goals and latest regulatory requirements on global level.
- Cross-Functional Collaboration: Partner with manufacturing, quality assurance, quality control, regulatory affairs, clinical operations, development, patient safety and other stakeholders to ensure timely and thorough management of GxP and quality incidents.
- Root Cause Analysis and CAPA management: Drive and support comprehensive root cause investigations. Drive and oversee the development of corrective and preventive actions plans and lessons learned related to escalated GxP and Quality incidents. Drive initiation and execution of market actions, if required.
- Regulatory and GxP Compliance: Ensure that the GxP / Quality incident management related activities and documentation meet the relevant regulatory agency and other relevant requirements for the industry (FDA, EMA, any local regulations, ISO, WHO); prepare for and support inspections and audits.
- Health authority interactions: Drive and facilitate notification and communication with health authorities on global level.
- Training & Communication: Develop and deliver training on incident management procedures, share lessons learned from managed GxP/Quality incidents and promote a culture of quality and accountability across the organization.
- Metrics & Reporting: Ensure meeting of key performance indicators (KPIs), track incident trends, and provide regular reports.

Minimum Requirements:

- Education: University degree in a life sciences field (advanced degree preferred, e.g. pharmacist, biochemist, biologist, chemist, biotechnologist).
- Extensive experience (typically 12+ years) in quality assurance, quality control, quality systems, compliance, manufacturing and/or development within a GxP-regulated environment. **Experience with classical pharmaceuticals, biologics and ideally ATMPs.**
- Demonstrated leadership in incident management, CAPA processes, regulatory inspections and communication with health authorities.
- Strong knowledge of global GxP regulations and other pharmaceutical guidelines and regulations.
- Excellent communication, analytical, and problem-solving skills.

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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.

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部门
Operations

Business Unit
Quality

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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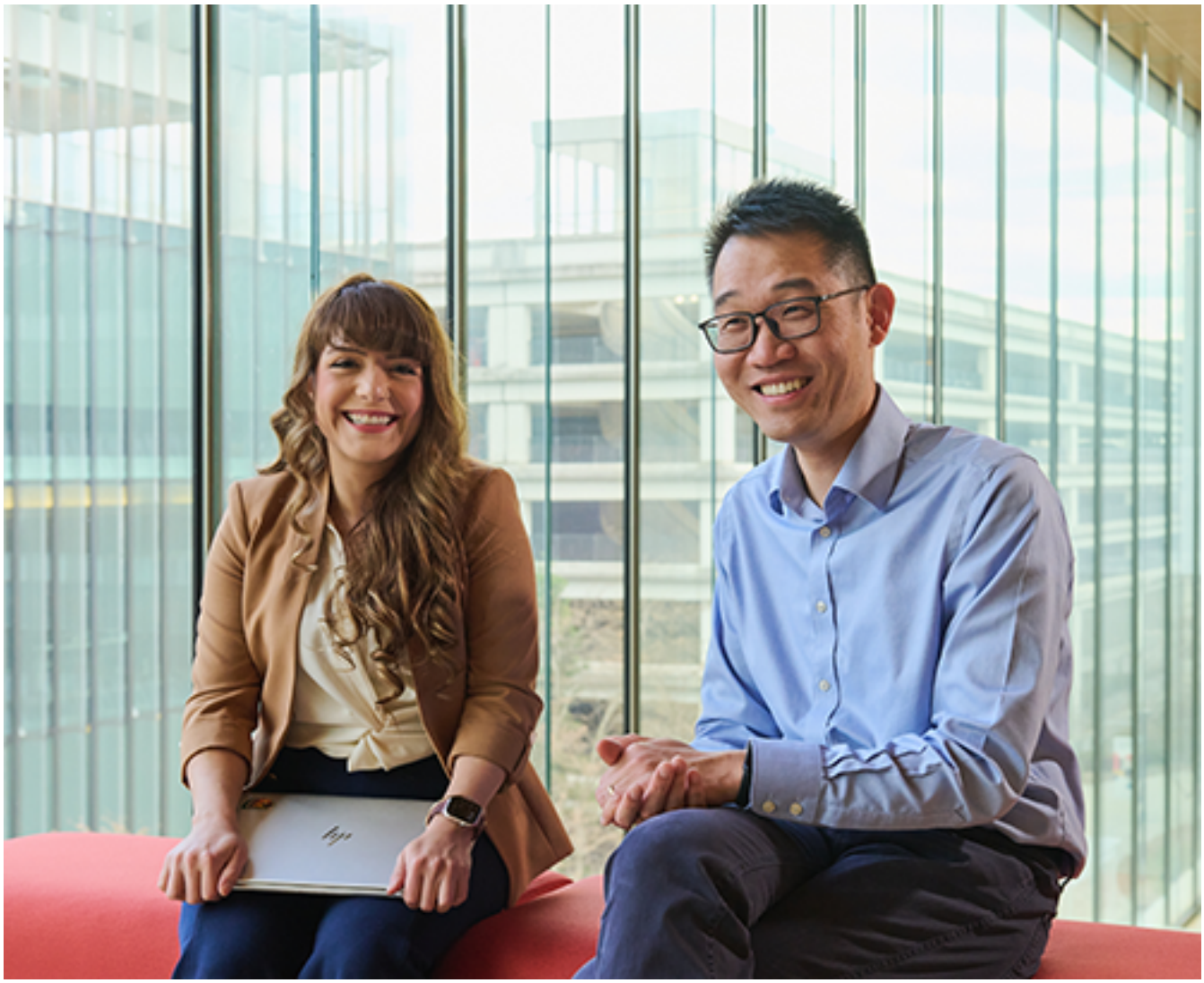

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