R&D Quality Specialist

Job ID
REQ-10059152

8月 12, 2025

India

摘要

The Quality Specialist manages user access for critical applications, creates and updates training materials, authors and maintains SOPs, supports end-user onboarding, coordinates with IT for user access issues, oversees document management and archival, and owns quality processes including change controls, CAPAs, and investigations.

About the Role

Key Responsibilities:

- Oversee user access management for designated applications, ensuring timely provisioning, modification, and deactivation in line with compliance standards. Develop, update, and maintain training materials and user guides related to application usage and quality processes.
- Author, revise, and maintain Standard Operating Procedures (SOPs) relevant to application

management and QA workflows.
- Provide end-user support for onboarding, including training delivery and troubleshooting access or usage issues. Act as the primary liaison with IT teams to resolve user access issues and coordinate on application enhancements or changes.
- Support and document application enhancement activities, including requirement gathering, testing, and user communication. Handle GXP document archival processes, ensuring compliance with document management procedures.
- Troubleshoot document management issues such as document transfer failures, incorrect archival location, and naming convention errors.
- Maintain accurate records of user access, training completion, SOP updates, and document archival for audit readiness.

- Own and manage change controls, serving as the designated owner for quality events, CAPAs (Corrective and Preventive Actions), and investigation actions. Approve quality events and ensure timely closure of related actions.
- Contribute to continuous improvement initiatives within the QA team and support cross-functional projects as needed.

Minimum Requirements

- Bachelor ' s degree in Life Sciences, Computer Science, or related field.
- 2+ years ' experience in quality, IT support, document management, or user access management roles in a regulated environment (pharma preferred).
- Strong understanding of compliance, data integrity, document management, and quality event processes.
- Excellent communication and collaboration skills.
- Experience with application onboarding, training, SOP authorship, and quality event ownership is highly desirable.

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部门
Development

Business Unit
Universal Hierarchy Node

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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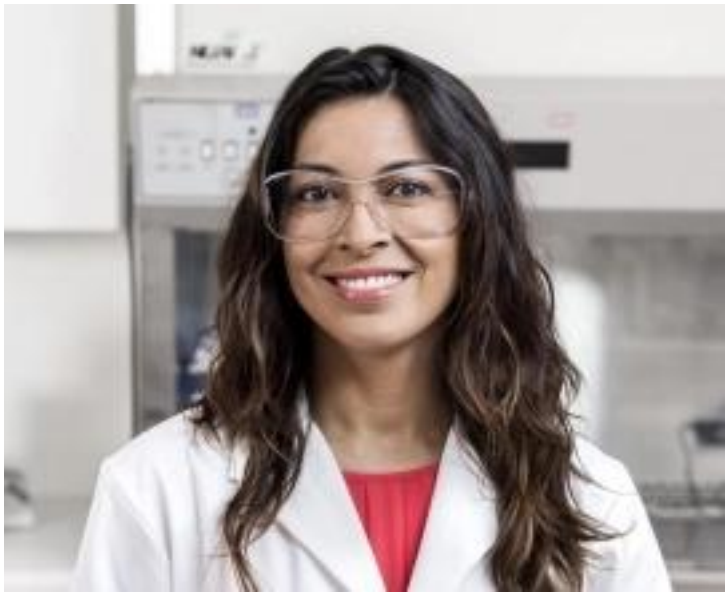

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