Specialist, Quality operations

Job ID
REQ-10067815

12月 02, 2025

India

摘要

-Manages Quality aspects and projects within area of responsibility. -Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems.

About the Role

Key Responsibilities:

- · Coordination and management of analytical method transfers and stability studies. Compilation of data reports
- · Life-cycle management of analytical methods, including control of method performance, pharmacopoeia and health authority compliance and definition of method improvements. Handling of deviations, investigation, OOS/OOE/OOT cases as well as changes and complaints
- · Perform statistical data analysis to report Out of Expectations (OOE), out of trends

(OOT), etc

- · SAP master data management: Maintenance of master data, creation of Q-info records and other SAP related activities.
- · Validate spreadsheets
- · Collect, transcribe and/or compile data from various repositories (SAP, LIMS, external COAs)
- · Author, approve and archive Impurity risk assessments - Nitrosamines, residual solvents, etc
- · Trend and report all QMS elements as per the request
- · Monitor, trend and report Health Safety and Environmental parameters
- · Implementation of GMP requirements. Compilation and Review of documents (analytical protocols and reports, annual performance quality reports, ongoing process verification reports, registration documents (Common Technical Document modules)).
- · Perform activities of a Quality Control expert as defined by the respective sites
- · Support regulatory requirements - routine queries, Chromatogram requests
- · Compile Quality performance management decks
- · Create and review GxP documents including SOPs, working procedures, trend reports, qualification reports and technical investigations, as and when needed

Key performance indicators:

- · On-time and GMP-compliant release of dosage forms -No complaints about inspections by authorities in your own area of responsibility without these being noticed and communicated beforehand -Successfully support continuous improvement projects

Essential Requirements:

· Pharmacy/ Science/ MBA / Engineering/ equivalent from a reputed institute

· Min 6 years of experience in Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substances/ products/ medical devices

· GxP knowledge, Basic IT knowledge

· Good communication, presentation and interpersonal skills

· Experience of working closely with the global stakeholders

Desirable Requirements:

· Continuous Learning.

· Dealing With Ambiguity.

· Gmp Procedures.

· Qa (Quality Assurance).

· Quality Control (Qc) Testing.

- Quality Standards.
- Self Awareness.
- Technological Expertise.
- Technological Intelligence.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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部门
Operations

Business Unit

Other

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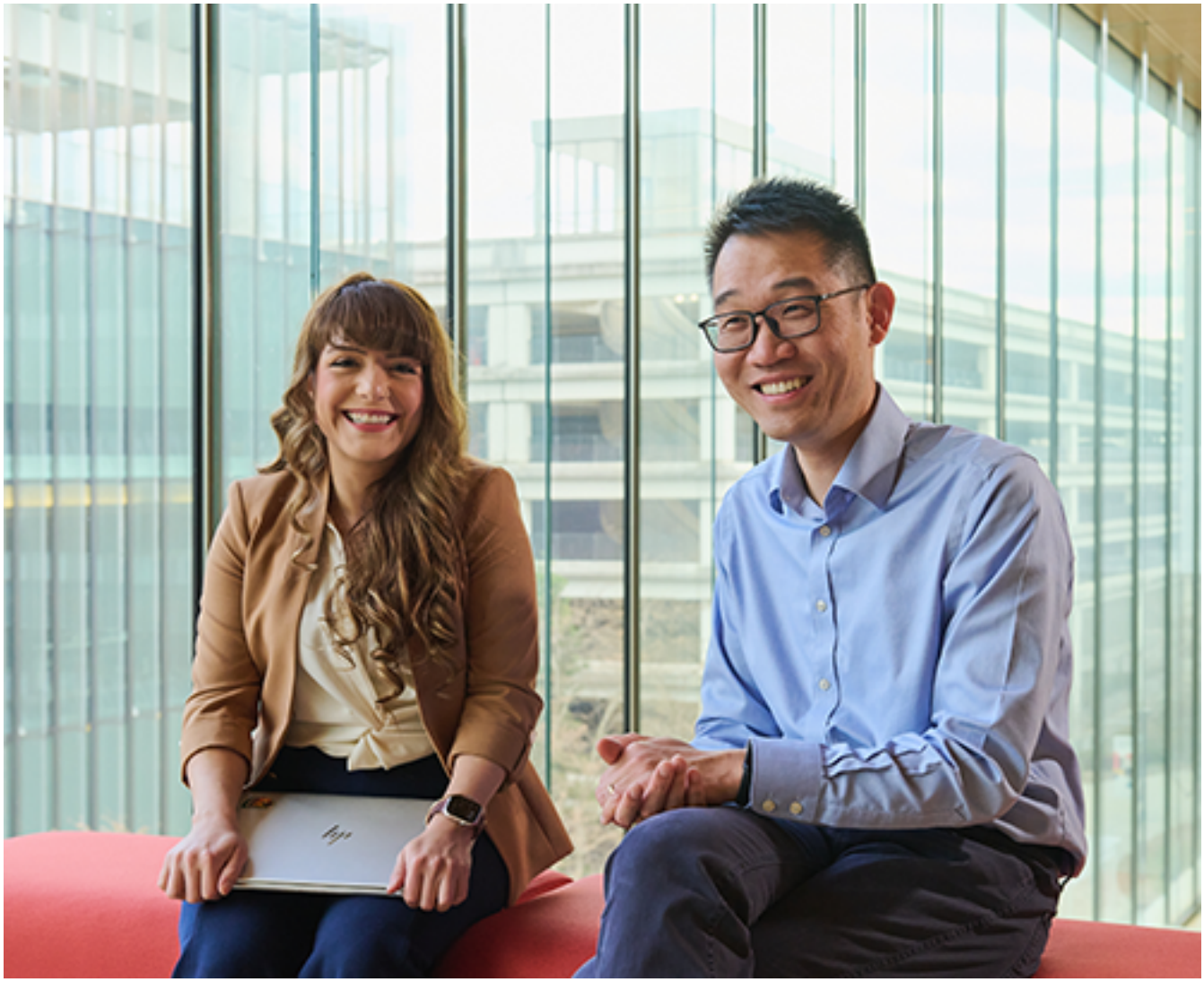
Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.



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