

Quality Assurance Operations Specialist

Job ID
REQ-10086513
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Индия

Сводка

The Quality Assurance Operations Specialist provides quality services in compliance with cGMP requirements and Novartis Quality Management System as defined and agreed between QOP and business partners. Manages Quality aspects & projects within area of responsibility.

About the Role

Major Accountabilities:

- Comply with internal procedures and systems, including KPI reporting, ticket management, time tracking, workflow applications, and other functional processes.
- Support business needs through ad hoc administrative activities, assigned tasks, trainings, and ownership of deliverables with accuracy and timeliness.
- Communicate regularly with customers, partners, sites, suppliers, CMOs, and internal teams to gather feedback, coordinate activities, and support service delivery.
- Ensure adherence to Novartis quality standards, GxP requirements, regulatory expectations, operating procedures, and applicable legal, IT, and P&O requirements.
- Create, review, analyze, and maintain GxP documentation and reports, including SOPs, working procedures, trend reports, qualification reports, technical investigations, and ad hoc reports.
- Support audits, quality operations, product quality compliance, regulatory workflows, CAPA management, process improvements, and Master Data Management activities as required.
- Manage complaints by receiving, reviewing, processing, investigating, approving, trending, reporting, and closing complaint records in applicable QMS tools.
- Coordinate complaint-related activities with CMOs, suppliers, Country Organizations, sites, and complaint hubs, including documentation, sample availability, supplier investigations, deviations, actions, and follow-up activities.

Obligatory Requirements:

- Education in **Pharmacy, Science, MBA, Engineering**, or an equivalent qualification from a reputed institute.
- Minimum **3 years of experience** in Quality Assurance, Regulatory, or manufacturing of pharmaceutical drug substances, products, or medical devices.
- Strong understanding of **GxP requirements** and basic IT knowledge.
- Fluent in **English**, both written and spoken.
- Good communication, presentation, and interpersonal skills.
- Experience working closely with **global stakeholders**.

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>

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

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.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>.

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: Learn about all the ways we'll help you thrive personally and professionally.

[Read our handbook \(PDF 30 MB\)](#)

Дивизион
Operations
Business Unit
Other
Место
Индия
Сайт
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

Accessibility and accommodation

Novartis is committed to working with and providing 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 diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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