

# Country Quality Specialist

Job ID  
REQ-10014447  
Sep 03, 2024  
Indien

## Summary

Monitor quality governance and compliance in the Country organization in all GxP related areas (Supply chain, C&F Ware house, Market Compliant, etc) to ensure that all aspects of the operational business comply with cGxP, legal and regulatory requirements and the Novartis Pharma Corporate Quality Manual and Policies.

Prevent significant quality issues or regulatory non-compliance which could lead to product stock-out or withdrawal, product approval delays or which would negatively impact the financial performance of the company as well as the reputation.

## About the Role

### Country Quality Specialist

**Location** - Hyderabad

#### About the Role:

Monitor quality governance and compliance in the Country organization in all GxP related areas (Supply chain, C&F Ware house, Market Compliant, etc) to ensure that all aspects of the operational business comply with cGxP, legal and regulatory requirements and the Novartis Pharma Corporate Quality Manual and Policies.

Prevent significant quality issues or regulatory non-compliance which could lead to product stock-out or withdrawal, product approval delays or which would negatively impact the financial performance of the company as well as the reputation.

#### Key Responsibilities:

- Ensure implementation, maintenance and upgrading of the local Quality System and Standard Operating Procedures in order to drive compliance of all cGXP and Pharmacovigilance related processes and tasks with local/International regulatory requirements and the Novartis Quality Manual.
- Actively involved in ensuring quality governance and quality planning in the Country organization through the establishment and implementation of the annual Quality Plan, appropriate Key Quality Indicators, and Quality Risk Assessments.
- Ensure that a local Quality System and Standard Operating Procedures are in place for all GxP related activities and that compliance with cGMP is maintained through training and internal audits.
- Ensure that all drug products are released in accordance with the registered specifications and are released to the market in accordance with local regulations and ensure that a respective Change Control procedure is in place. (Batch Release).
- Ensure that all aspects of the handling and distribution of pharmaceutical products at Novartis India

Limited through Central Warehouse & C & F's comply with the requirements of the Novartis Pharma Quality Manual and Policies and meet all relevant cGMP, regulatory and legislative requirements.

- Visit, supervise and co-ordinate CPO Vendors(C&Fs, Sticking site etc) activities and ensure that vendor perform the respective activities are in compliance with Novartis Standards.
- Participate in resolving all Critical Quality Issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc) according to the Quality Assurance Agreement and the Novartis Pharma Quality Manual. Ensure investigations are correctly executed. Ensure they are updated in AQWA (Adaptable Quality Workflow Application)
- Ensure that Change requests, either from the External Supplier/Vendor or from Novartis CPO, are managed according to the Quality Assurance Agreement and/or Novartis SOPs from receipt, through to the implementation and closure.
- Responsible for preparing Quality trends and driving Continuous improvement for processes and product quality performance.
- Provide the quality presence and in-put to Compliance / Technical meetings with the CPO Vendors and establish good working relationships with clear communication and defined actions and goals. In addition, provide support to internal functions (BD&L, CRO and other functions) by evaluation and decision of new products as per Novartis Pharma Quality Manual and standards. Perform the required periodic review and make recommendations for amendments to the evaluation based on identified needs and issues.

#### **Essential Requirements:**

- 2-3 years in QA / QC.
- Knowledge of cGMP and regulatory compliance of all relevant operations like C and F cold chain etc.
- Proficient in communicating with vendors and internal customers. Good in presentation skills
- Interacting with people from interface functions in the local organisation. Support for resolving GMP and GxP related issues.

#### **Desirable Requirements:**

- B.Sc., B.Pharm Post graduate Diploma added advantage
- Fluent in English and proficient in local language.

**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>

**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>

**Join our Novartis Network:** Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

**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>

TEst Hello

Division

Operations

Business Unit

Innovative Medicines

Standort

Indien

Site

Mumbai (Head Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

[Apply to Job](#)

**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>

**Join our Novartis Network:** Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

**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>

The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Job ID

REQ-10014447

## Country Quality Specialist

[Apply to Job](#)

---

**Source URL:** <https://dev1.novartis.de/careers/career-search/job/details/req-10014447-country-quality-specialist>

### List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. <https://www.novartis.com/careers/benefits-rewards>
4. [https://novartis4.wd3.myworkdayjobs-impl.com/en-US/Novartis\\_Careers/job/Mumbai-Head-Office/Country-Quality-Specialist\\_REQ-10014447](https://novartis4.wd3.myworkdayjobs-impl.com/en-US/Novartis_Careers/job/Mumbai-Head-Office/Country-Quality-Specialist_REQ-10014447)
5. <https://www.novartis.com/about/strategy/people-and-culture>
6. <https://talentnetwork.novartis.com/network>
7. <https://www.novartis.com/careers/benefits-rewards>
8. [https://novartis4.wd3.myworkdayjobs-impl.com/en-US/Novartis\\_Careers/job/Mumbai-Head-Office/Country-Quality-Specialist\\_REQ-10014447](https://novartis4.wd3.myworkdayjobs-impl.com/en-US/Novartis_Careers/job/Mumbai-Head-Office/Country-Quality-Specialist_REQ-10014447)