

# Specialist - Quality Operations

Job ID  
REQ-10015156  
Sep 03, 2024  
India

## Summary

-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

### Major accountabilities:

- Oversight of all production and testing activities, ensures compliance with cGxP, incl. data integrity and eCompliance -Support exception investigations -Review and approval of production, QC, and AS and T records -MBR review -Support OpEx improvement projects Qualified Person – Executes batch release in compliance with registration -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

### 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 -Executes batch release in compliance with registration

### Minimum Requirements:

#### Work Experience:

- Functional Breadth.
- QC/ QA in pharmaceutical ind./ biotech with environmental monitoring &.
- Collaborating across boundaries.
- cleanliness zones.

### Skills:

QMS

BMR/ BPR review

Batch Release process

Quality Management

Regulatory compliance checks

**Languages :**

- English.

**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>

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Division

Operations

Business Unit

Innovative Medicines

Location

India

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Alternative Location 1

Telangana, India

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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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](mailto: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.

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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