

## 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.

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部門  
Operations

部門  
Innovative Medicines

国  
India

勤務地  
Hyderabad (Office)

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

Alternative Location 1  
Telangana, India

Functional Area  
Quality

職種  
Full time

雇用形態  
Regular

Shift Work  
No

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