

# **Specialist - Quality Operations**

Job ID REQ-10015156 Sep 03, 2024 Inde

#### Résumé

-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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Division

Operations

**Business Unit** 

Innovative Medicines

Emplacement

Inde

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Alternative Location 1

Telangana, Inde

**Functional Area** 

Qualité

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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