# **U** NOVARTIS

# **Specialist - Quality Operations**

Job ID REQ-10015176 Sep 03, 2024 India

### Resumen

-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

Job Description

#### 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** 

#### 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? <a href="https://www.novartis.com/about/strategy/people-and-culture">https://www.novartis.com/about/strategy/people-and-culture</a>

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División Operations **Business Unit** Innovative Medicines Ubicación India Sitio 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 Apply to Job

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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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# **Specialist - Quality Operations**

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