

# Specialist - Quality Operations

Job ID
REQ-10015156

9月 03, 2024

India

### 摘要

-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	Minimum	Rec	uirer	ments
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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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# 部门 Operations **Business Unit** Universal Hierarchy Node 地点 India 站点 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 Apply to Job

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