

Major accountabilities:

# **Specialist - Quality Operations**

Job ID REQ-10015176
9月 03, 2024
India
摘要
-Manages Quality aspects and projects within area of responsibilityEnsures and supports overal GxP conformity and Compliance with the Novartis Quality Management Systems.
About the Role
Job Description

 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.

<ul> <li>QC/ QA in pharmaceutical ind./ biotech with environmental monitoring &amp;</li> <li>Collaborating across boundaries.</li> <li>cleanliness zones.</li> </ul>
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? <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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部门 Operations **Business Unit Innovative Medicines** 地点 India 站点 Hyderabad (Office) Company / Legal Entity IN10 (FCRS = IN010) Novartis Healthcare Private Limited **Functional Area** Quality Job Type Full time

Employment Type Regular

Shift Work

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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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