

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	Rec	uire	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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이 Departions
Business Unit Production / Manufacturing
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

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representative of the patients and communities we serve.
Accessibility and accommodation Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.
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