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:
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
Innovative Medicines

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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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.

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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