Specialist-Quality Operations

Job ID
REQ-10024461

10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:

- Exposure in handling of customer/market complaints, field alerts, recalls and conducting investigations. Can independently handle meetings/ discussion with business partners/ suppliers.
- Experience in creating Quality assurance agreement and Quality risk assessment for Contract manufacturers / suppliers.
- Understanding on Audits & CAPA management for suppliers.
- Strong understanding on Quality Management System and GxP requirements.

- Provide support in preparation, review and approval of GMP documents including local and global SOPs, WP ' s, Investigation reports, etc., where required.
- Ensure implementation of applicable Novartis QMS requirements in the function.
- Provide support as key user/ Super user for IT tools used for Quality Management System.
- Provide timely and effective communication of any potential compliance gaps/ risks in respective function, the respective SPOCs or Team Lead and facilitate for resolution of identified gaps/ risks.
- Initiate, monitor and fulfill the timely review of APQR documents for all own site and Contract manufacturers.
- Provide quality support to Nitrosamine risk-based evaluation/ Changes, as required. Initiate and implement quality improvement/ simplification projects, wherever possible. Impart trainings on GMP/Data integrity and other relevant trainings, as required.
- Create various periodic performance metrics reports for respective GxP activities and share/ present to Business leaders/ partners.
- Author technical documents (like testing plans, testing monographs, Stability report etc.) and provide data driven technical and analytical insights to improve process understanding, quality and compliance of the product.
- Manage different type of change control like product stewardship/ Administration Stewardship /Asset Stewardship in electronic system like Agile PLM, from Change Initiation to closure as needed.
- Experience in Document Management tools and competency in MS office tools.
- Ensure all time readiness of the activities for internal/ Business partner audits (including data integrity audits), host audits, and manage audit action plans for timely closure of agreed CAPAs.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You ' ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

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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
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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