Specialist - Quality Operations

Job ID
REQ-10011765
Jun 14, 2024
India

Summary

This position is responsible to perform and deliver Quality Operations services in support of product quality compliance and regulatory workflows.

About the Role

Position Title : Specialist - Quality Operations

Location – Hyderabad

About the Role:
This position is responsible to perform and deliver Quality Operations services in support of product quality compliance and regulatory workflows.

Key Responsibilities:

• Escalate service related GxP and non-GxP issues and ensure timely investigation and compliance with local and global operating procedures. Support implementing service quality and process improvement projects, CAPA management within Quality Service Centers.
• Responsible for the extraction and data compilation of analytical, manufacturing (including deviations, complaints, and change requests) and regulatory data (HA commitments, variations) in a predefined format.
• Responsible for collecting stability data and reports for product related evaluations. (e. g. compliance Investigations, divestitures, product transfers, validation. Etc. Support maintenance of APR/PQR schedule.
• Follow-up and tracking of complaint sample availability from Country Organization (CO) to CMO (Contract Manufacturing Organization). Send technical complaints to CMO for investigation. Perform queries in AQWA/Trackwise as per the SOP.
• Perform Quarterly compliant trending and reporting. Perform the role of QA approver for customer complaints delegated to QSC through delegated action.
• Perform a role of change control coordinator or change phase manager in change control management systems like TrackWise and AGILE. Manage different type of change control like product stewardship/Administration Stewardship/Asset Stewardship.

Commitment to Diversity & Inclusion: :

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Role Requirements :

Essential Requirements:

• M. Pharm/ MBA / Engineering/equivalent from a reputed institute.
• 5+ years' experience in QA/Documentation management, Change management/GXP/QMS
• GxP-knowledge, Broad IT-knowledge
• Good communication, presentation and interpersonal skills. Experience of working closely with the global stakeholders
• Experience on MAH review, quality compliance management, technical learning & document management system, product release support, stability support services.

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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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? https://www.novartis.com/about/strategy/people-and-culture

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Division
Operations
Business Unit
Innovative Medicines
Location
India
Site
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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Job ID
REQ-10011765

Specialist - Quality Operations

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