NOVARTIS

Associate Manager - Quality Operations

Job ID
REQ-10029448
Nov 13, 2024
India

About the Role

Key Responsibilities:

- Perform and deliver Quality Operations services in support of product quality compliance and regulatory workflows
- Hold accounts in workflow applications (such as SAP, Dragon, SUBWAY, etc.) to ensure appropriate execution of service deliverables
- Generate and analyze predefined and ad-hoc reports in various applications (like AGILE PLM, AQWA etc.) and perform follow-up actions if required
- Escalate service related GxP and non-GxP issues and ensure timely investigation and compliance with local and global operating procedures.
- Ensure compliance to the Novartis internal quality standards, relevant regulatory requirements, filed product quality standards and service level agreements.
- Support implementing service quality and process improvement projects, CAPA management within Quality Service Centers.
- Comply with all internal functional operating procedures like time tracking, KPI reporting, ticket management tools and other internal systems and processes.
- Regularly communicate with customers and partners to collect feedbacks on support services, report deliverable.
- Focus on timely completion of all relevant and assigned trainings
- Learn & develop understanding to generate insights through data and digital.
- Ensure responsibility and ownership of the assigned tasks
- Comply the accuracy and timeliness of deliverables
- Comply to the applicable Novartis operating procedures as per legal / IT / HR requirement
- Create and review GxP documents including SOPs, working procedures, trend reports, qualification reports and technical investigations.
- Lead / transition new service or expansion projects, monitor and report progress and deviations, as

appropriate.

- Adherence to the service KPI’s and ensuring the service dashboard, order management framework and time sheet is always kept updated.
- Train, develop or mentor personnel for successful and timely onboarding in Quality Operations
- Provide active support during internal and external audits by collecting and presenting the requested process data/reports
- Hold accounts and develop understanding on trouble shooting in workflow applications (such as SAP, Dragon, SUBWAY, etc.)

Essential Requirements:

- M.Pharm/ MBA / Engineering/equivalent from a reputed institute
- Min 6 Yrs experience in Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substances or products/ Medical device, expertise in LMS
- GxP-knowledge, Broad IT-knowledge, Proficient in MS-Office
- Excellent communication, presentation and interpersonal and analytical skills
- Experience of working closely with the global stakeholders.
- Project Management skills

Role Requirements

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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Benefits and Rewards: Read our handbook to learn about all the ways we’ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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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