Associate Manager - Quality Operations

Job ID
REQ-10029448
nov 13, 2024
Inde

Résumé

Provide quality services in compliance with cGMP requirements and Novartis Quality Management System as defined and agreed between QSC and business partners. Manage Quality aspects & projects within area of responsibility.

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

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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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Qualité
Job Type
Full time
Employment Type
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Shift Work
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