

## Associate Manager - Quality Operations

Job ID  
REQ-10029448

11月 13, 2024

India

### 摘要

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

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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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