NOVARTIS

Analyst Quality Operations

Job ID
REQ-10023160
Sep 20, 2024
Inde

Résumé

-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

Common Accountabilities: (Applicable to all services in QOP)

- Comply with internal functional requirements such as KPI reporting, ticket management tools and any other internal procedures and processes
- Assist the department on any other ad hoc activities/ requests to meet the business requirements
- Regularly communicate with partners and obtain feedback on services delivered
- 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 with accuracy and timeliness of deliverables
- Comply to the applicable Novartis operating procedures as per legal/ IT/ P&O requirements
- Create and review GxP documents including SOPs, working procedures, trend reports, qualification reports and technical investigations, as and when needed
- Provide active support during internal and external audits by collecting and presenting the requested process/ data and reports
- Adherence to the current GxP and compliance policies of Novartis 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, TEDI etc.) to ensure appropriate execution of service deliverables
- Generate and analyze predefined and ad-hoc reports in various applications (such as 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
- Comply with all internal functional operating procedures like time tracking, KPI reporting, ticket management tools and other internal systems and processes
- Assist the department on any other ad hoc administrative activities as per business requirements
- Regularly communicate with customers and partners to collect feedbacks on support services, report deliverable

☐ **Change Control Management:**

- Manage different types of change control like product stewardship/Administration Stewardship/Asset Stewardship in electronic systems like Agile from Change Initiation to closure as needed
- Generate and analyze predefined and ad-hoc reports in various applications and perform follow-up actions as required.
- Perform Regulatory assessment on Change Controls as needed.
- Perform deviation investigations and CAPAs as part of change management.

Ideal Background / Requirements for the role:

- M. Pharm/ MBA / Engineering/equivalent from a reputed institute.
- Min 6 yr Experience in Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substances/ products/Medical device.
- GMP -knowledge, Broad IT-knowledge
- Fluent in English (written and spoken)
- Good communication, presentation and interpersonal skills
- Experience of working closely with the global stakeholders

Languages :

- English

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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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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