Quality Manager - TRD

Job ID
REQ-10009101
Juni 05, 2024
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Summary

Provide quality assurance with minimum experience on handling IT systems to provide guidance and support to operational activities in development and research organizations to ensure compliance with applicable regulatory requirements and Novartis procedures and quality standards.
-Manage projects, including Quality Plan initiatives, and processes that support quality objectives to assure their compliance with GxP regulations.

About the Role

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Key Responsibilities:

- TRD QA Manager as Business System Owner for IT application is responsible for overall development, maintenance, integration, operation of GXP validated system.
- Plays vital role in system enhancements to ensure operational requirements are documented, tested and implemented as per IT Waterfall Methodology.
- Acts as a single point of responsibility for application for ensuring the system and data are secured as required by Information Security and Compliance requirements.
- Is responsible to identify IT system upgrades to enhance system performance and mitigate the recurrent application issues / bug fix.
- Represents the application in integrated Landscape and works with other Platforms (i.e. SAP, IRT etc) for mitigation of issues at interface level.
- Support Internal audits / health authority inspections.
- Provide assistance in the remediation of deviations related to IT systems, ensure follow up and monitoring of associated corrective and preventive actions.
- Review and approve the IT system validations reports.

Essential Requirements:

- 9+ years of practical experience in chemical / pharmaceutical industry or > 3 years of experience in field of expertise

- Working Knowledge Drug Development process or QA
- Experience on handling IT systems as Key user / Super User/ System Owner
- Basic project management, good organization and planning skills
- Knowledge of relevant regulations (e.g. GMP, HSE etc.) and Novartis specific standards.

Desirable Requirements:

- Bachelor / Masters Degree with experience in Pharmaceutical Industry/ specifically GMP background.

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