eCompliance Manager

Job ID
REQ-10011709
Sep 03, 2024
India

Summary

Manage cost effective GxP Compliance and/or Audit activities, operations and systems to ensure compliance of business areas with the Novartis Quality Manual and Policies and all relevant GxP, legal and regulatory requirements, and through internal audits, KPIs (Key Performance Indicators) and KQIs (Key Quality Indicators) -Performs preparation and management of external and corporate audits and Health Authority inspections.

About the Role

eCompliance Manager

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The eCompliance Manager is responsible for providing Quality Assurance oversight and guidance with regard to computerized systems validation (CSV), operating within the framework of regulations (GxP, 21CFR11, etc.) and requirements defined in the Novartis Quality Manual and global procedures.

eCompliance Manager provides the needed operational support such as approving the GxP impacted changes, Periodic Review Reports, deviations etc., Provides the guidance to the project and operations team on the CSV related topics and related information. Reviews and/or approves the global Computerized Systems key validation deliverables as a part of the eCompliance support to the GxP projects.

Key Responsibilities:

- Quality oversight of operational activities of GxP systems (e.g., Changes, Periodic Reviews, Deviations etc.,)
- Provide needed support to meet the applicable Novartis and regulatory requirements for GxP regulated computerized systems projects.
- Point of Contact for all CSV related matters for GxP Computerized Systems and act as an interface between IT and Business for eCompliance topics in relation to GxP classified Computer Systems promoting a Quality Culture.
- Review and approve project related documents for GxP relevant systems including determination of GxP applicability for all GxP and non-GxP relevant systems.
- Establish trusted partnership with assigned IT Function with understanding of business drivers, and provide the needed day to day operational support.
- Review and approve the GxP Changes and the associated deliverables.
- Review and approve the GxP impacted deviations, ensure appropriate CAPA are implemented.
- Contribute for the preparation of VMP and execute the plan for the systems associated with the

respective functions.
- Review and approve the Periodic Review Reports for the GxP computerized systems and the associated gaps within CAPA Management System.
- Manage GxP supplier qualification activities
- Provide Audit support as assigned and in case of CAPAs, provide the required Quality support.

Essential Requirements:

- 10-15 years of overall IT experience, and a minimum 7 years of relevant experience in the Pharmaceutical Industry and in particular within regulated functions such as IT Quality and Compliance
- Solid understanding of global regulations and Health Authorities expectations governing computerized systems (CSV, Part 11, etc.)
- Solid experience in the development, implementation and lifecycle management of computerized systems in regulated environments
- Experience in quality management of Cloud, SaaS platform, mobile and digital application used in regulated environments
- Highly experienced in the operational management of GxP solutions including its related technologies to support the operation
- Good understanding in system application management, its Quality support approach and industry best practices (ITIL, ITSM, etc.)
- Experience in the development, implementation and lifecycle management of key computerized systems in the Pharmaceutical Development, Manufacturing, Quality, Commercial and Infrastructure space (e.g. ERP/SAP, MES, LIMS, CRM, IAM, etc.)

Desirable Requirements:

- Degree in Information Technology, Life Sciences, Pharmacy, Engineering or equivalent.

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Employment Type
Regular
Shift Work
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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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