eCompliance Manager

Job ID REQ-10065610

10月 24, 2025

India

摘要

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.

About the Role

Major accountabilities:

- Quality oversight of operational activities of GxP systems (e.g., Changes, PeriodicReviews, Deviations etc.,)
- Provide needed support to meet the applicable Novartis and regulatoryrequirements for GxP regulated computerized systems projects.
- Point of Contact for all CSV related matters for GxP Computerized Systems and actas an interface between IT and Business for eCompliance topics in relation to GxPclassified Computer Systems promoting a Quality Culture.
- Establish trusted partnership with assigned IT Function with understanding ofbusiness drivers, and provide the needed day to day operational support.includingdetermination of GxP applicability for all GxP and non-GxP relevant systems.
- Review and approve the GxP Changes and the associated deliverables.
- Review and approve the GxP impacted deviations, ensure appropriate CAPA areimplemented.
- 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.
- Perform supplier qualification assessment activities.
- Provide Audit support as assigned and in case of CAPAs, provide the requiredQuality support.

Key performance indicators:

- GxP relevant computerized systems are developed, implemented andmaintained according to the Novartis requirements.
- On time review and approval of changes, deviations & periodic reviewreports for the GxP computerized systems.
- Documentation supporting eCompliance and CSV requirements is in place, maintained up-todate and can be presented during audits and inspections without delays and issues.
- Gaps in eCompliance and CSV activities are proactively identified, escalatedand the development of mitigation plans supported.
- Client/stakeholder satisfaction and corresponding feedback.

Minimum Requirements: Degree in Information Technology, Life Sciences,

Pharmacy, Engineering or equivalent Work Experience:

- 10-15 years of overall IT experience, and aminimum 7 years of relevant experience in thePharmaceutical Industry and in particular withinregulated functions such as IT Quality andCompliance
- Solid understanding of global regulations and Health Authorities expectations governingcomputerized 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 applicationused in regulated environments
- Highly experienced in the operationalmanagement of GxP solutions including its related technologies to support the operation
- · Good understanding in system applicationmanagement, its Quality support approach

- andindustry 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.)
- Successful cross-divisional/functional work withcomplex international teams
- Experience in GxP supplier qualification activities
- Proven ability to adjust to multiple demands, shifting priorities and unexpected events whilemaintaining a positive work attitude
- Ability to effectively interact and present toManagement
- Ability to manage the key stakeholders and buildtrust
- Proven ability to influence without hierarchicalauthority and build trusted partnerships
- Proven self-starter with experience in initiating and delivering projects and processes
- Excellent communication, negotiation, facilitation, and interpersonal skills

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部门 Development

Business Unit Pharma Research

地点 India

站点 Telangana
Company / Legal Entity IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area Quality
Job Type Full time
Employment Type Regular
Shift Work No

Accessibility and accommodation

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