

Senior eCompliance Manager

Job ID

REQ-10088597

Oct 05, 2026

LOC_IN

About the Role

Key Responsibilities:

- Ensure implementation of the e-Compliance strategy and all applicable Novartis and regulatory requirements for all GxP and AI regulated computerized systems and associated infrastructure.
- Contribute to developing a future-focused strategy for AI and emerging technology readiness, evaluating regulatory requirements and developments to ensure the Novartis QMS remains fit for purpose in the eCompliance environment.
- Lead the implementation, scaling and adoption of approved automation and AI capabilities within assigned eCompliance domains.
- Provide oversight, and guidance in the development and implementation of Novartis GxP computerized Systems and processes, including on-going implementation of Data Integrity technical controls within IT systems landscape.
- Single Point of Contact for all CSV related matters for GxP Global 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.
- Establish trusted partnership with assigned IT Function with understanding of business drivers, strategic roadmap and its impact on the eCompliance team.
- Review and approve project related documents for all Global GxP relevant systems including determination of GxP applicability. Review and approve High Level Classification & Consultation Document (HLCCD), standards and documents for all Global GxP and non- GxP relevant systems including determination of GxP applicability.
- Support the life-cycle of GxP computerized systems with periodic re-evaluation of the validation status, change controls, deviations management ensuring that relevant documentation is in place and maintained according to the Novartis requirements.
- Closely cooperate with functional IT staff in the compliant development and delivery of computerized systems to meet GxP requirements.
- Provide the needed e-Compliance support for the Strategic Projects, audits and Inspections.
- Ensure that the KQIs are proactively managed.
- Support the development, maintenance and effective implementation of appropriate standards and non-contradictory processes for governing GxP computerized systems.
- Support appropriate benchmarking with industry for trends and changing regulations to ensure that the Novartis standards and requirements are sustainably maintained and aligned and compliant with current HA requirements and expectations. Integrate into internal NVS regulatory processes accordingly.
- Support the development and implementation of adequate eCompliance standards in established quality risk assessment processes to ensure that eCompliance and technical requirements for data integrity are adequately covered.
- Perform supplier qualification assessment activities.

Essential Requirements:

- Full time Bachelor's or Master's degree with 15-20 years of overall experience, and a minimum 10 years of relevant experience in the Pharmaceutical Industry and in particular within regulated functions such as IT Quality and Compliance.

- Profound understanding of global regulations and Health Authorities expectations governing computerized systems incl. computerized systems validation, lifecycle management and 21 CFR Par 11 requirements.
- Solid experience in the development, implementation and lifecycle management of computerized systems in regulated environments.
- Experience in quality management of onsite, 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.).
- Successful cross-divisional/functional work with complex international teams.
- Proven ability to adjust to multiple demands, shifting priorities and unexpected events while maintaining a positive work attitude.
- Ability to effectively interact and present to Management, health authority inspectors.
- Proven ability to influence without hierarchical authority and build trusted partnerships.
- Proven self-starter with experience in initiating and delivering projects and processes.
- Excellent communication, negotiation, facilitation, and interpersonal skills.

Desirable Requirements:

- Proficiency in data governance, data integrity, analytics, Power BI and KPI/KQI management.
- Strong understanding of cloud/SaaS, cybersecurity, RPA, APIs, Agile/DevOps and modern computerized systems.
- Understanding of GenAI, Agentic AI, machine learning, automation, digital twins and other emerging technologies.
- Experience in digital transformation initiatives.

Role Requirements

Division

DIV_TO

Business Unit

Quality

Location

LOC_IN

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

FCT_QA

Job Type

Full time

Employment Type

Regular

Shift Work

No

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