# Sr. eCompliance Specialist

Job ID
REQ-10035976

Jan 08, 2025

India

## Summary

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

**Location - Hyderabad**

**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.
- Perform supplier qualification assessment activities.
- Provide Audit support as assigned and in case of CAPAs, provide the required Quality support.

**Essential Requirements:**

xP relevant computerized systems are developed, implemented and maintained according to the Novartis requirements. On time review and approval of changes, deviations & periodic review reports for the GxP computerized systems.

2. Documentation supporting eCompliance and CSV requirements is in place, maintained up-to-date and can be presented during audits and inspections without delays and issues.

3. Gaps in eCompliance and CSV activities are proactively identified, escalated and the development of mitigation plans supported.

4. Client/stakeholder satisfaction and corresponding feedback.

**Desirable 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.)
- Successful cross-divisional/functional work with complex international teams
- Experience in GxP supplier qualification activities
- 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
- Ability to manage the key stakeholders and build trust
- 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

**Commitment to Diversity and Inclusion:**

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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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

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Operations

部門
Innovative Medicines

国
India

勤務地
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Quality

職種
Full time

雇用形態
Regular

Shift Work
No

Apply to Job.

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