

eCompliance Manager

Job ID
REQ-10088584
Сен. 28, 2026
Индия

Сводка

About the role:

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

Key Requirements:

- Quality oversight of operational activities of GxP systems (e.g., Changes, Periodic Reviews, Deviations etc..)
- Drive the design, deployment and continuous improvement of automation and AI-enabled solutions within assigned processes.
- Provide needed support to meet the applicable Novartis and regulatory requirements for GxP regulated computerized systems projects.
- Supports the development of future-focused strategy in AI and emerging technologies readiness, evaluating regulatory requirements and developments to ensure Novartis QMS is fit for purpose in the eCompliance environment.
- 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.
- 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:

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

- 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

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<https://www.novartis.com/about/strategy/people-and-culture>

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Дивизион

Operations

Business Unit

Quality

Место

Индия

Сайт

Hyderabad (Office)

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

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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