

Sr. eCompliance Specialist

Job ID
REQ-10088594
Сен. 28, 2026
Индия

Сводка

About the role:

The Senior eCompliance Specialist 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.

Sr. eCompliance Specialist 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 Project and 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. Support the implementation, operation and optimization of automation and AI-enabled solutions in day-to-day eCompliance activities.
- 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 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. Provides audit support as assigned and in case of CAPAs, provides the required Quality support.

Essential Requirements:

- Degree in Information Technology, Life Sciences, Pharmacy, Engineering or equivalent.
- 5-10 years of overall experience, and a minimum 4 years of relevant experience in the Pharmaceutical Industry within particular in regulated functions such as IT Quality and Compliance
- Good understanding of global regulations and Health Authorities expectations governing computerized systems (CSV, Part 11, etc.)
- Good experience in the development, implementation and lifecycle management of computerized systems in regulated environments
- Experienced in the operational management of GxP solutions including its related technologies to support the operation. Experience in GxP supplier qualification activities

Desirable Requirements:

- Good understanding in system application management, its Quality support approach and industry best practices (ITIL, ITSM, etc.)
- Experienced in the development, implementation and lifecycle management of key computerized systems in the Pharmaceutical Development, Manufacturing, Quality, Commercial and Infrastructure space
- Successful cross-divisional/functional work with complex international teams
- 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 influence without hierarchical authority and build trusted partnerships
- Self-starter with experience in initiating and delivering projects and processes
- Excellent communication, negotiation, facilitation, and interpersonal skills

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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

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