

Senior eCompliance Manager

Job ID
REQ-10029642
Dec 03, 2024
India

Summary

Ensure implementation of applicable Novartis and regulatory requirements for all GxP regulated computerized systems and associated infrastructure. 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. Closely cooperate with functional IT staff in the compliant development and delivery of computerized systems to meet GxP requirements.

Review and approve CSV deliverables for all Global GxP relevant systems including determination of GxP applicability.

About the Role

Key Responsibilities:

- 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 NBSQ eCompliance team.
- Review and approve project related documents for all Global GxP relevant systems including determination of GxP applicability. Review and approve High Level Risk Assessments (HLRA), 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
- Support the measurement of KQIs and execution of DI Plan.
- Support the development, maintenance and effective implementation of appropriate standards and non-contradictory processes for governing GxP computerized systems.

Essential Requirements:

- 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 standard processes (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
- Demonstrable 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;
- Demonstrable ability to influence without hierarchical authority and build trusted partnerships
- Proven self-starter with experience in initiating and delivering projects and processes
- Superb communication, negotiation, facilitation, and interpersonal skills

Desirable Requirements:

- Degree or equivalent experience in Life Sciences, Pharmacy, Engineering or Information Technology; advanced degree preferred.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other.

Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?

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

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Division

Operations

Business Unit

Innovative Medicines

Location

India

Site

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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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.

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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