NOVARTIS

Senior eCompliance Manager

Job ID
REQ-10029642
Nov 12, 2024
India

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.

Role Requirements

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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Senior eCompliance Manager

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