Senior eCompliance Manager

Job ID
REQ-10065412

10月 26, 2025

India

摘要

Ensure implementation of the e-Compliance strategy and all 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:

Data Integrity: Serve as the Data Integrity Champion for the organization, promoting ALCOA+ principles and compliance culture. Establish and maintain data integrity governance frameworks, policies, and procedures in accordance with GxP and regulatory requirements. Lead/Support awareness programs and training sessions to strengthen organizational understanding and ownership of data integrity.

People Management: Lead and develop a high-performing team, providing direction, coaching, and performance feedback. Foster a culture of accountability, collaboration, and continuous learning within the team. Manage workload distribution, goal setting, and career development for team members.

Stakeholder Management: Collaborate closely with cross-functional teams (such as QA, IT, Manufacturing, Labs, Regulatory, and Operations) to ensure quality and compliance principles are integrated into business processes. Align stakeholders to support process improvements, change management, and compliance initiatives.

Desirable Requirements:

- 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 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
- 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, health authority inspectors;
- 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

Work Experience:

- 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

Education: Degree in Life Sciences, Pharmacy, Engineering or Information Technology; advanced degree preferred.

Languages :

- Fluency in English (oral and written)

Why Novartis: Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You ' ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

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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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部门
Operations

Business Unit
Quality

地点
India

站点
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

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