Sr. eCompliance Specialist

Job ID
REQ-10055110

6月 30, 2025

India

摘要

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

Major accountabilities:

- 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.
- 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
- GxP relevant computerized systems are developed, implemented and maintained according to the Novartis requirements.
- On time review and approval of changes, deviations & periodic review reports for the GxP computerized systems.
- Documentation supporting eCompliance and CSV requirements is in place, maintained up-to-date and can be presented during audits and inspections without delays and issues.Gaps in eCompliance and CSV activities are proactively identified, escalated and the development of mitigation plans supported.Client/stakeholder satisfaction and corresponding feedback.

cation and validation activities (planning, advising, review) -Supports the implementation of Quality Systems (incl. documentation management); Ensure local DI and eCompliance oversight (training, inspections, plan, risk ID etc) -Ensure process quality assurance according to regulations

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部门
Operations

Business Unit
Innovative Medicines

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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