

Sr. eCompliance Specialist

Job ID
REQ-10026556

10月 22, 2024

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.

Key performance indicators:

- 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.

Minimum Requirements:

Work Experience:

- 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

Skills:

- 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
- 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
 - Education:
- Degree in Information Technology, Life Sciences, Pharmacy, Engineering or equivalent
- 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> Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>.

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>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

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

[Apply to Job](#)

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.



Job ID
REQ-10026556

Sr. eCompliance Specialist

[Apply to Job](#)

Source URL:

<https://www.novartis.com.cn/careers/career-search/job/details/req-10026556-sr-ecompliance-specialist>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. <https://www.novartis.com/careers/benefits-rewards>
4. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/Sr-eCompliance-SpecialistREQ-10026556>
5. <mailto:diversityandincl.india@novartis.com>
6. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/Sr-eCompliance-SpecialistREQ-10026556>