NOVARTIS

Head e-Compliance DDIT Commercial & Development

Job ID
REQ-10058924

8月 10, 2025

India

摘要

Lead DDIT, Commercial and Development eCompliance Team in the development and implementation of eCompliance Strategy for DDIT, Commercial and Development.

Modernizes technology, and enhances Quality Assurance oversight within DDIT, Commercial and Development in line with GxP requirements

Identifies, measures, remediates, and monitors regulatory risks associated with eCompliance in DDIT, Commercial and Development in line with GxP requirements.

Collaborates with eCompliance stakeholders, cross-functional partners, Data Integrity colleagues, and key stakeholders while employing strategic thinking to drive initiatives forward.

Drive the AI readiness and competency building for the E-Compliance organization by identifying and ensuring training staff on AI technologies, integrating AI with existing compliance systems, and ensuring data integrity and security.

About the Role

Head e-Compliance DDIT Commercial & Development

Location - Hyderabad #LI Hybrid

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Key Responsibilities:

- Strengthens QA oversight of the IT activities within DDIT, Commercial and Development, including preparing for regulatory inspections and ensuring ongoing inspection readiness.
- Develops a future-focused strategy in AI and emerging technologies readiness, evaluating regulatory requirements and developments to ensure Novartis QMS is fit for purpose in the eCompliance environment.
- Establishes robust risk management strategies covering all areas of eCompliance for Technical Operations. Ensures that eCompliance risks are captured in Enablon/iRisk and escalated accordingly.
- Provides leadership for quality systems oversight and the management of GxP computerized systems. Collaborates effectively with Quality & IT business partners in DDIT, Commercial and Development, eCompliance personnel across Novartis, and other divisional quality and business functions to ensure the delivery of quality outcomes.
- Functions as a quality system owner for CSV within the Novartis Quality Manual.
- Provides quality inputs into IT-related vendor selection, qualification, and management

processes.
- Establish governance model for continuous feedback, engagement and to drive simplification through standardization. Establish pro-active eCompliance monitoring & reporting based on a. Audit & inspection findings b. DI challenges and c. NVS functional level eCompliance related challenges
- Strengthen external collaborations to get Industry benchmarking and to get more insights on the new regulatory requirements and Health Authority expectations for the computerized systems, proactively identify them and get them adapted into the internal processes and systems.

Commitment to Diversity & Inclusion: :

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Essential Requirements:

- A minimum of 15 years of relevant experience, specifically within regulated functions such as Quality Compliance, and/or IT.
- Profound understanding of global regulations governing the lifecycle management of computerized systems, and how they apply to new technologies such as AI.
- Strong leadership presence, with a proven ability to effectively communicate, interact and influence key stakeholders without hierarchical authority.
- Excellent communication, negotiation, consulting/facilitation, and interpersonal skills.
- Outstanding facilitation skills for bridging between scientific and business stakeholders, and for man-aging effective and successful international and cross-divisional collaborations.
- Strong change management abilities.
- Demonstrated strength in applying strategic thinking, scenario evaluation and contingency planning.
- Strong organizational awareness and business acumen (e.g. interrelationship of departments, business priorities), including significant experience working cross-functionally and in global and matrix teams.

Desirable Requirements:

- Extensive knowledge of Regulatory and Quality requirements in the area of CSV.
- Strategic thinking and creative problem-solving skill
- Self-motivated with a high degree of ownership and accountability for results.

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

Commitment to Diversity and Inclusion:
Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.
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
Universal Hierarchy Node

地点

India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Alternative Location 1
Ljubljana, Slovenia

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.

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