NOVARTIS

Quality Manager (ecompliance)

Job ID
REQ-10078211
май 15, 2026
Индия

Сводка

Provide quality assurance expertise, guidance and support to operational activities in development and research organizations to ensure compliance with applicable regulatory requirements and Novartis procedures and quality standards. Manage projects, including Quality Plan initiatives, and processes that support quality objectives to assure their compliance with GxP regulations. Responsible for operational eCompliance support for Biomedical Research, ensuring compliance, validation oversight, and inspection readiness for GxP and non-GxP systems and associated supplier activities.

About the Role

Key Responsibilities

- Support initiatives to maintain or improve quality performance and compliance of operational activities including risk management, health authority reporting, IT systems
- Manage and Support quality aspects of projects and activities, including those related to third parties, analytical instruments, manufacturing equipment, quality plans, training, IT validations, etc.
- Provide operational eCompliance support for ~20 active systems (GxP and non-GxP), including Periodic Review, review of validation and change control deliverables, HLCCD review and sign-off
- Support operational aspects of new system implementations, ensuring adherence to compliance and validation requirements
- Perform technical aspects of IT / Technology Vendor Qualification and assessments
- Provide inspection support for systems supported by the eCompliance manager
- Provide input on technical aspects of SOPs, guidance, standards, and health authority (HA) regulation gap assessments
- Support operational aspects of CAPAs and remediation activities, including review of CAPA documentation

Minimum Requirement

- Bachelor’s degree with ~5 years of experience or Master’s degree with ~2 years of experience in quality, compliance, or clinical development.
- Strong experience in audit & inspection management, quality management systems (QMS), quality assurance, and regulatory compliance across drug development.
- Proven expertise in SOP management and working within GxP-regulated environments (GCP, GLP, GMP).
- Solid understanding of computer system validation (CSV), change control processes, and IT supplier qualification and audits.
- Demonstrated experience supporting inspection readiness with strong attention to detail and regulatory alignment.

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

Benefits and Rewards: Learn about all the ways we’ll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Development
Business Unit
Development
Место
Индия
Сайт
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

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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