U NOVARTIS

Analyst - Quality Operations

Job ID REQ-10026688 Oct 21, 2024 India

Resumen

-Manages Quality aspects and projects within area of responsibility. -Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems.

About the Role

Major accountabilities:

- 1. Handling of Audit CAPA actions, Deviations and Investigations.
- 2. Preparation of annual audit plans
- 3. Monitoring and maintain of KQI's and KPI's.2.
- 4. Maintenace of Shrepoints and Repositories. ·

5. Responsible to update the information on SharePoint/ trackers, review the applicable documents for correctness and archival of necessary documents on SharePoint.

6. Provide Administrative support in preparation of Quality Management Review meeting slide deck & metrics reporting.

7. Preparation, approval, and management of QAA's.

8. Develop and maintain process SOPs, working procedures and process maps. ·

9. Provide support for GMP External Audits and inspection management activities (HA and Self Inspection Audits).

10. Maintain Approved supplier list for GxP vendors.

11. Preparation of UQAP (Unified Quality Audit Program), Audit preparation support and QARP (Quality assurance responsible Person) Role for audit CAPA Management.

Minimum Requirements:

M.Pharm/ equivalent from a reputed institute.

• Min 4-6 yr Experience in Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substances or products/ Medical device.

Basic awareness of GxP compliance requirements. 1/3

Work Experience:

• QMS Knowledge w.r.t. deviations, Investigations, handling of CAPA.

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

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

División Operations **Business Unit** Innovative Medicines Ubicación India Sitio 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 <u>diversityandincl.india@novartis.com</u> 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.

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