U NOVARTIS

QA Team Head - (Genome Valley)

Job ID REQ-10037193

1月 23, 2025

India

摘要

Lead the group, manage resources and capacities. Leading and managing a team with team leads and/or quality individuals at TRD GV sites QA function. Accountable for team objectives and deliverables as per objective setting. Supervise, guide and support global TRD project teams in all quality-relevant topics, questions, and issues. Develop project strategies in alignment with TRD considering all relevant cross-functional aspects to ensure the quality of deliverables within the project.

About the Role

Major accountabilities:

• Lead and manage team, budget and resources according to objectives. Manage global TRD project team and represent TRD QA globally in TRD sub-teams, as well as at global quality board meetings and project development gate meetings.

- Ensure quality oversight on the assigned development projects with strong quality guidance, scientific and technical expertise.
- 1. Experience in 3rd party management.
- 2.Experience in Manufacturing and analytical operations.
- 3. Data and digital technologies.
- 4. Advanced People Management skills.
- 5. Advanced Stakeholder Management and communication skills.
- 6.Agile and flexible
- Contribute to the strategy of assigned projects incl. contingency planning and risk assessments as appropriate to ensure timely achievement of project quality deliverables. Ensure that the strategy followed within the assigned projects is in line with TRD QA strategies and goals and in compliance to cGMP guidelines and internal procedures.
- Understand and proactively manage the interactions of project related activities between TRD QA and other departments inside or outside of TRD.
- Proactively communicate overall project strategy, key issues and any other critical topics in a timely manner to the appropriate management level, to the TRD project leader and/or to any other relevant project team member(s).
- Represent TRD QA in Due Diligence teams and provide quality assessment of potential inlicensing products in a timely manner and support follow-up activities as appropriate.
- Provide input to contracts and QA agreements with 3rd parties. Approve project-specific QA agreement amendments for assigned projects.
- Lead or participate in global and/or cross-functional initiatives.
- Prepare and guide TRD project teams for Mock-PAI and PAI in the frame of the PAI preparation process and submission preparation.
- Coach and mentor functional experts. Participate in recruiting process.

Minimum Requirements:

Education -

- Masters (15 years ' pharma quality or operations) and 3-5 experience in people Management.
- Fundamental, broad understanding and knowledge of quality standards and policies in Drug Substance/Drug Product/Medical Devices manufacturing and control.
- Experience with Health Authority Inspections (FDA and EMA in particular), and knowledge of RegCMC requirements for Health Authority submissions (INDs, IMPDs, NDAs, ANDAs, MAAs). Broad experience in technical drug development as well as in Quality Assurance and/or Quality Control departments.
- Experience in Technical Operations or equivalent experience from external company is preferred.
- Proven track record in successfully leading interdisciplinary teams, e.g. scientists working on technical or methodological projects, in TRD or equivalent experience from external company or other line function.
- Ability to contribute to matrix teams with the necessary strategic thinking, quality awareness and implementation skills.
- Computer literacy (e.g. MS Office, document management systems) demonstrated along with readiness to learn new systems and associated processes. Excellent organizational and project management as well digitalization skills. Ability to influence people, negotiate and communicate.

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: <u>https://www.novartis.com/about/strategy/people-and-culture</u>

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <u>https://www.novartis.com/careers/benefits-rewards</u>

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.

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

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? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

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: <u>https://www.novartis.com/careers/benefits-rewards</u>

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

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