

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 in-licensing 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.

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部门
Development

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

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