R&D Quality Manager

Job ID
REQ-10054414

6月 16, 2025

India

摘要

Independent Project work less complexity, e.g. early phase projects. Lead or support smaller and less complex projects or support more complex projects with mentoring. Higher complex routine tasks e.g. failure investigations and deviation, change controls etc. Manage projects and processes to support departmental portfolio, projects and objectives according to agreed timelines and standards. Ensure that compliance with cGMP is maintained in TRD.

About the Role

Key Responsibilities

- Support a discipline and/or provide a service individually or within a team of associates. May provide functional expertise to Line Unit and other QA Units in area of responsibility
- Write review, decide on approval and/or release of GMP-relevant deliverables and/or related tools as per area of responsibility in order to ensure compliance with cGMP and project

quality deliverables.

- Manage project related activities (e.g. TRD product portfolio, development of new tools, processes, Quality initiatives, Quality Manual implementation, Quality Plans, Quality Risk Assessments, training activities, qualification and facility upgrade activities, IT validation projects) as per area of responsibility.
- Support Project management functions as a project team member.
- Provide support to TRD line functions in GMP related topics as per area of responsibility.
- Comply with internal and external guidelines regarding quality and safety (Quality Manual, regulatory cGMP guidelines, Health Authority guidance, SOPs etc.).

- Manage a Design History File / Tech File portfolio of assigned Medical Device/ Drug Device Combination projects from Quality perspective and provide functional expertise in responsibility for medical devices and combination products in cross-functional project teams to assure cGMP Compliance with medical device specific regulations (ISO 13485:2016, EU MDR, 21 CFR 820 and 21 CFR Part 4) and internal Novartis standards for Medical Device development products under submission and Life Cycle Management activities. He/She ensures the quality specific tasks of a Design History File and follow-up including supporting medical device reporting to regulatory authorities.
- Monitoring, analysis, and reporting of GMP related KPIs as part of management reporting, Review QA agreements for Medical Device projects. Coordinate complaint investigations for Medical Device projects. Review of release documentation for medical device components.
- Support PMS activities for Medical Device projects. Support QMS and Audit (external and internal) activities

Minimum Requirements:

- Masters, Bachelor/Technician (> 5 years ' pharma)
- Fluent English required (oral & written) Good skills in site (local) language desired.
- Good knowledge of cGMP, working knowledge in technical development, production or QA.
- Sound scientific, technical and regulatory knowledge.
- Good organizational and decision-making skills.
- Good and proven ability to analyze and evaluate cGMP compliance.

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

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
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

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 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.

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

Job ID
REQ-10054414

R&D Quality Manager

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10054414-rd-quality-manager

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/R-D-Quality-ManagerREQ-10054414
5. mailto:diversityandincl.india@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/R-D-Quality-ManagerREQ-10054414