Quality Manager

Job ID
REQ-10066773

11月 24, 2025

USA

摘要

-Provide quality assurance expertise, guidance and support to operational activities in development and research organizations to ensure compliance About this role:

The Quality Manager is responsible for product development for new product supporting IND filing through the BLA filing. Product scope includes cell therapy products and gene therapy products.. Support compliance during development, manufacturing, analytical testing and tech transfer. Performing batch release activities and managing deviations and escalations related to the product.

Location: East Hanover NJ, #LI- Hybrid

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.).

Essential Requirements:

- Bachelor's Degree and at least 10 years' pharma quality or pharma operations
- Fundamental, broad understanding and knowledge of quality standards and policies in Drug Substance/Drug Product/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).
- Good experience in technical drug development as well as in Quality Assurance and Quality compliance departments.
- Experience in Technical Operations or equivalent experience is preferred.
- Ability to contribute to matrix teams with the necessary strategic thinking, quality awareness and implementation skills.
- Computer literacy 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.

Novartis Compensation and Benefit Summary: *The salary for this position is expected to range between $98,700 and $183,300/year. The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors. Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.*

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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

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The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Development

Business Unit
Quality

地点
USA

状态
New Jersey

站点
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Quality Manager

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