TRD QA Team Lead, CMC

Job ID
REQ-10060900

9月 04, 2025

USA

摘要

About this role:

The TRD QA Team Lead CMC is responsible for overseeing the product quality group and ensuring compliance for products in the portfolio from early development to late phase clinical. Drive the oversight of quality management systems and initiatives within the global, regional, and country organization, ensuring compliance with applicable health authority regulatory requirements (e.g., GCP, GLP, GMP, PV, IP) and Novartis procedures and quality standards. Role model good quality behaviors while promoting a culture of quality (e.g., right first time, etc.) to positively impact the non-quality stakeholders (e.g., NIBR, GDD). Develop, drive and/or support Quality plan initiatives in order to achieve organizational strategy, mission and vision

Location: East Hanover NJ, #LI- Hybrid

About the Role

Key Responsibilities:

- Provide QA expertise and guidance to ensure compliance with requirement of the quality system are met, including implementation of quality risk-based and GxP-relevant process.
- Lead and manage a QA product quality team and collaborate with business partners and other quality groups to ensure health authority and regulatory requirements are fully met
- Translate functional QA strategy into applicable operational/compliance activities and support a risk-based implementation and execution of processes.
- Ensure quality and compliance gaps are addressed and executed for sustainability and implement strategic process improvement, including review of procedural updates, training, process improvement, effectiveness checks, etc.
- Work with team for escalations, risk and issue management to support product manufacturing testing and supply at NVS sites and at third parties.
- Support quality oversight/management of external service providers supporting activities and drive facilitation and follow-up of audits and inspections, and ensure development, implementation and completion of appropriate corrective and preventive measures for findings
- Ensure timely escalation of deviation/incidents and provide quality oversight for deviations/incidents, including robust investigations, root cause analysis and corrective actions implementation.
- Contribute towards lessons learned based on audits, inspections, incidents, regulatory intelligence, effectiveness checks on process implementations and metrics and support a culture of proactive, risk-based behavior
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Essential Requirements:

- Bachelor ' s degree required; Master ' s degree preferred.
- Minimum of 10 years ' pharma quality or operations that includes at least 3 years ' experience in people management
- Fundamental, broad understanding and knowledge of quality standards and policies in Drug Substance and Drug Product manufacturing and control within CGT area.
- Experience with Health Authority Inspections (FDA in particular), and knowledge of RegCMC requirements for Health Authority submissions (INDs/IMPDs).
- Broad experience in technical drug development in CGT as well as in Quality Assurance and/or Quality Control departments.
- Experience in Technical Operations CGT or equivalent experience from external company is preferred.
- Proven track record in successfully leading interdisciplinary teams, e.g. working on technical or methodological projects, in TRD or equivalent experience from external company or other line function.
- Ability to influence people, negotiate and communicate.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $145,600 and $270,400/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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

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
Universal Hierarchy Node

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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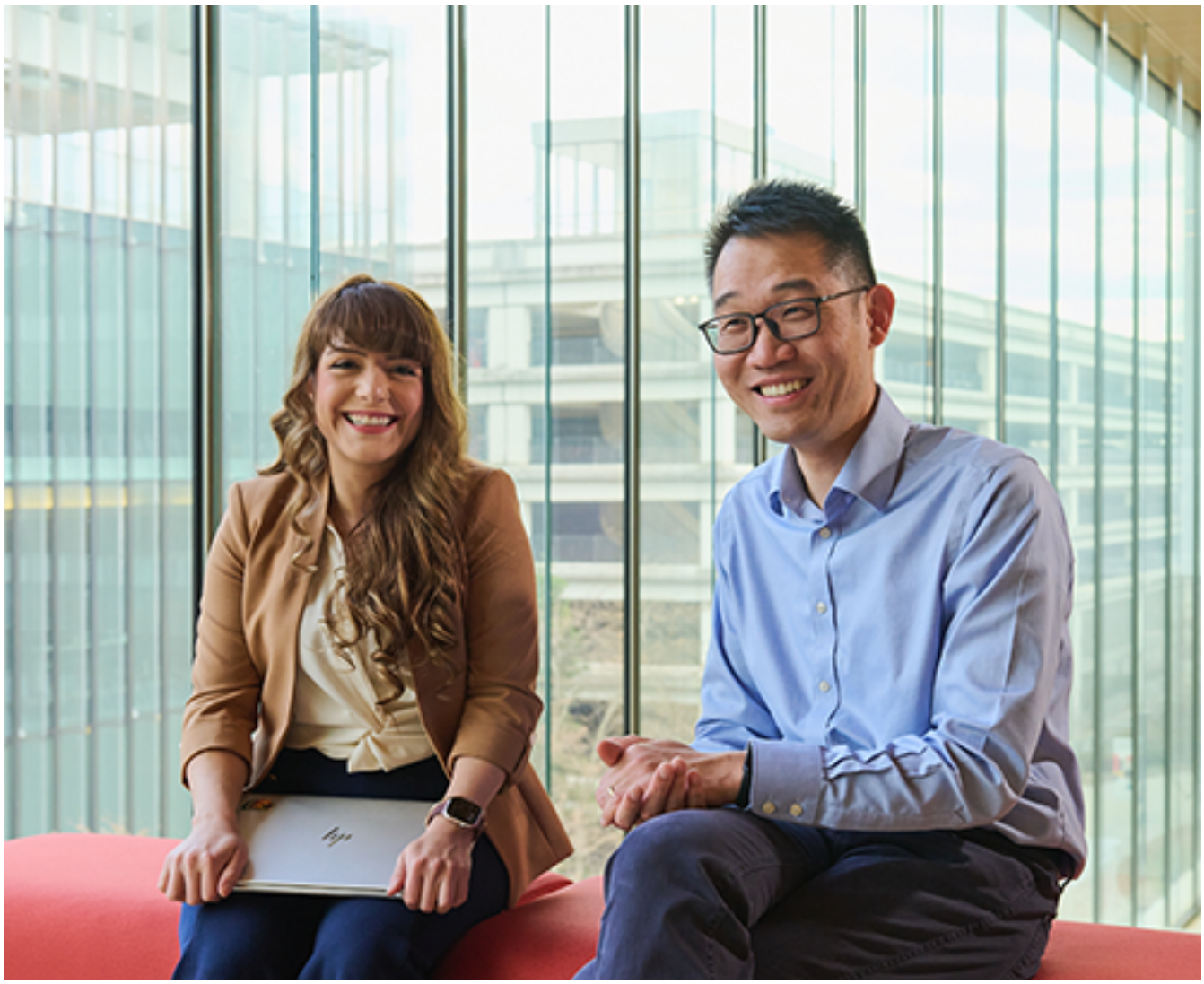

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