RLT Quality Operations Lead - US (Remote)

Job ID
REQ-10063883

10月 02, 2025

USA

摘要

#LI-Remote

At Novartis, we are pioneering the future of cancer treatment through Radioligand Therapy (RLT) - a powerful fusion of nuclear medicine and precision oncology. As we expand our global RLT manufacturing footprint, we are seeking passionate, purpose-driven individuals to join our mission of delivering life-changing therapies to patients around the world.

The RLT Quality Operations Lead US, is a senior leadership role accountable for the end-to-end quality operations across all US RLT manufacturing facilities. This position sets the operational model for US quality operations, ensures compliance to international cGMP standards, Novartis rules and applicable market regulatory requirements, drives inspection readiness and success, and develops high-performing quality teams. The role oversees up to five US locations supporting both domestic and multiple ex-US markets.

This position can be based remotely anywhere in the U.S. (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager. This

position will require 25% travel.

About the Role

Key Responsibilities:

- Provide strategic leadership and governance for Quality Operations across all US RLT manufacturing sites, ensuring consistent standards, processes, and performance.
- Ensure compliance with applicable regulations and standards (e.g., FDA, cGMP, ICH, Health Authority expectations) and alignment with global Quality policies and procedures.
- Lead inspection readiness and the execution of health authority, customer, and internal inspections; drive robust CAPA, remediation, and continuous improvement.
- Oversee site-level Quality functions (e.g., QA Operations, QC Laboratories, Batch Release, Deviation/Investigation Management, Change Control, Supplier Quality, Validation, Documentation Control).
- Partner with Manufacturing, Supply Chain, MS&T, Regulatory Affairs, EHS, and Global Quality to enable reliable, compliant supply to US and ex-US markets.
- Ensure robust product quality oversight for RLT products, including radiopharmaceutical-specific controls, aseptic and sterile manufacturing practices, and distribution considerations. Champion safety, ethical compliance, and patient-centric decision making in all quality activities.
- Drive harmonization of quality systems and digital tools across sites; sponsor standardization, data integrity, and lifecycle management initiatives. Foster Networking and best practice sharing between the sites and regions.
- Lead talent strategy for US Quality Operations: workforce planning, capability building, succession, mentoring, and culture of ownership and continuous improvement.
- Own risk management for US sites: conduct quality risk assessments, implement mitigation plans, and ensure escalation/communication to senior leadership. Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt
- Manage budgets and resources for Quality Operations; optimize spend while safeguarding compliance and product quality.

Essential Requirements:

- Bachelor ' s degree in a scientific discipline (Pharmacy, Chemistry, Chemical Engineering, Radiopharmacy, Nuclear Medicine, or related field).
- 12+ years of progressive Quality/GxP experience in pharmaceuticals or biologics, including 7+ years in radiopharmaceuticals or sterile/aseptic operations.
- Previous experience as a Site Quality Head.
- Must have a working knowledge of FDA/EMA/ICH regulatory requirements. Proven track record of successful regulatory inspections (FDA and ex-US authorities), CAPA management, and quality system deployment.
- Strong people leadership: building teams, developing talent, leading through influence in matrix organizations.
- Excellent collaboration, communication, and stakeholder management skills; ability to operate

at strategic and tactical levels.
- Experience with global supply networks supporting multiple markets and product lifecycle stages
- Approximately 25% travel required.

Desirable Requirements:

- Advanced degree preferred.
- RLT experience strongly preferred.

The salary for this position is expected to range between $204,400 and $379,600 per 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. To learn more about the culture, rewards and benefits we offer our people click here: novartis-life-handbook.pdf.

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
Operations

Business Unit
Innovative Medicines

地点
USA

状态
Remote, US

站点
Remote Position (USA)

Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.

Functional Area
Quality

Job Type
Full time

Employment Type

Regular

Shift Work
No

Apply to Job

Job ID
REQ-10063883

RLT Quality Operations Lead - US (Remote)

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10063883-rlt-quality-operations-lead-us-remote

List of links present in page

1. https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://talentnetwork.novartis.com/network
4. https://www.novartis.com/careers/benefits-rewards
5. mailto:us.reasonableaccommodations@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Remote-Position-USA/RLT-Quality-Operations-Lead---US--Remote-REQ-10063883-1
7. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Remote-Position-USA/RLT-Quality-Operations-Lead---US--Remote-REQ-10063883-1