RLT Quality Operations Lead US (Remote)

Job ID
REQ-10068972

12月 22, 2025

USA

摘要

#LI-Remote
Proximity to an RLT site, especially Indianapolis, preferred.

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.

Are you ready to lead quality operations that directly impact patient safety and product excellence? As the RLT Quality Operations Lead for the US, you ' ll shape the future of radioligand therapy manufacturing, championing best practices and driving innovation across multiple sites. Join a team where your expertise will empower high-performing colleagues and ensure our therapies reach those who need them most.

About the Role

Key Responsibilities:

- Provide strategic leadership for quality operations across US radioligand therapy manufacturing sites.
- Define and implement the operating model for US quality operations, including organization design and performance management.
- Ensure compliance with current Good Manufacturing Practice (cGMP) standards and global Novartis quality policies.
- 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.
- Lead inspection readiness and successful execution of health authority, customer, and internal inspections.
- 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 international markets.
- Drive harmonization of quality systems and digital tools across sites, promoting data integrity and lifecycle management.

Essential Requirements

- Bachelor ' s degree in a scientific discipline required; advanced degree preferred.
- Minimum 10 years of progressive quality experience in pharmaceuticals or biologics, with at least 7 years in radiopharmaceuticals or sterile/aseptic operations.
- Previous experience as a Site Quality Head.
- Working knowledge of Food and Drug Administration (FDA), European Medicines Agency (EMA), and International Council for Harmonization (ICH) regulatory requirements.
- Proven track record of successful regulatory inspections, corrective and preventive action (CAPA) management, and quality system deployment.
- Strong people leadership skills, including team building, talent development, and stakeholder management.

The salary for this position is expected to range between $168,000 and $312,000 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.

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

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
Production / Manufacturing

地点
USA

状态
Remote, US

站点
Remote Position (USA)

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

Alternative Location 1
Indianapolis, Indiana, USA

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

Job ID
REQ-10068972

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