Global Head RLT Product Lifecycle (Remote)

Job ID
REQ-10059505

8月 12, 2025

USA

摘要

#LI-Remote
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 approximately 25% travel.

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.

As the Product Quality Lead you will play a crucial role in ensuring the quality and consistency of our products throughout their lifecycle. Your role will encompass a wide range of responsibilities that bridge clinical, development, and technical operations, providing expert guidance and leadership to ensure the highest quality standards for our products. You will drive a culture of quality through business partnering and supporting the quality mission and strategy. You will collaborate with various teams during different phases of product development, from preclinical to post approval changes.

About the Role

Key Responsibilities:

- Ensure establishment, maintenance and effectiveness of quality and data management systems and practices. Oversee all aspects of product lifecycle.
- Lead and manage a global QA organization and/or global quality project team and contribute to and regularly monitor the strategic milestones of the product lifecycle strategy.
- Ensure adherence to global and local safety and regulatory internal and health authority standards.
- Ensure adequate oversight of proactive quality risk management process including quality risk assessments and submission/inspection readiness activities.
- Support inspection preparation and facilitation and participate in audits and inspection follow-up activities including CAPA preparation.
- **End-to-End Product Quality Strategy** - Accountable for the overall product quality strategy, ensuring business continuity and managing product risks. This includes overseeing new lines, site transfers, validations, and analytical transfers.
- **Quality Oversight** - Provide expert quality guidance, technical support and quality leadership. Act as global quality lead in product related Quality escalations, recalls and BPDR handling. Support global site readiness for product pre-approval inspections across the LM platform / network. Maintain global quality oversight on Product Launch, Supply Chain, and Technology Transfers. Be involved in major product relevant investigations, particularly multi-sites deviations and significant recurring deviations, by leading or supporting site task forces in their investigations.
- **Regulatory Compliance -**Maintain oversight of product life cycle, including regulatory filings, product registrations, variation management, product introductions, launches, and technology transfers. Support inspection preparations.
- **Cross-Site Change Control -** Secure appropriate management of change controls across different sites to maintain consistent product quality, continuous quality improvement and product compliance. The responsibility of cross site changes is with Lead Site.

Essential Requirements:

- Undergraduate degree in Pharmacy, Chemistry, Biology or related subject; higher level degree preferred. Additional knowledge in Quality Assurance / Compliance
- 10+ years' experience in GMP-regulated industries including QA/QC in Biotech area.
- Working knowledge of FDA/EMA/ICH regulatory requirements
- Broad cGMP experience with knowledge and understanding of manufacturing, quality control, and validation requirements and activities.
- Ability to synthesize detailed information and clearly communicate across quality, manufacturing and supply chain.

The pay range for this position at commencement of employment is expected to be between $176,400 and $327,600 per year; however, while salary ranges are effective from 1/1/25 through 12/31/25 fluctuations in the job market may necessitate

adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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.

Alternative Location 1
Barcelona Gran V í a, Spain

Alternative Location 2
Ivrea, Italy

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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