Global Head Quality Compliance RLT (Remote)

Job ID
REQ-10062215

9月 24, 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 Global Head of Quality Compliance RLT is the enterprise leader responsible for designing, governing, and continuously improving the quality compliance strategy for radioligand therapies (RLT) across manufacturing, testing, release, distribution, and post-market surveillance. This role ensures global adherence to GxP requirements (GCP, GMP, GLP, GDP), nuclear/radiation safety regulations, and product-specific standards for radiopharmaceuticals across all regions.

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:

- Define and own the global Quality Compliance strategy for RLT, aligning with corporate objectives and regulatory expectations across the product lifecycle. Manage and develop a high-performing global quality compliance team; establish clear roles, talent pipelines, and succession plans.
- Establish, maintain, and continuously improve the Quality Management System (QMS) for RLT, including procedures, policies, digital quality systems, data integrity controls, and metrics. Develop and monitor quality KPIs and management reviews, present compliance status to executive leadership and governance boards.
- Oversee global inspection readiness and support regulatory inspections and partner audits (e.g., FDA, EMA, MHRA, PMDA, Health Canada) for RLT operations. Budget ownership for the Quality Compliance function.
- Ensure compliance with regulations and standards applicable to radiopharmaceuticals, including GMP for aseptic processing, Annex 1, sterile fill-finish, API/Drug Substance controls, and Good Distribution Practices for time- and temperature-sensitive, radioactive products.
- Lead the global internal audit program for RLT sites, CMOs, CROs, and key suppliers; ensure robust risk-based qualification and ongoing oversight.
- Serve as executive Quality decision-maker for significant deviations, OOS/OOT, change controls, CAPA effectiveness, and batch disposition policies; ensure independent QA oversight.
- Own global quality risk management, including product quality risk assessments, radiation safety interface, and business continuity planning for short-shelf-life products.
- Partner with Manufacturing, Supply Chain, Technical Operations, R&D, Pharmacovigilance, EHS, and Regulatory Affairs to ensure integrated, compliant, and efficient operations. Sponsor quality culture initiatives, training, and capability-building, emphasizing right-first-time, safety, and patient focus.
- Drive data integrity by design and computerized system compliance (e.g., Annex 11, 21 CFR Part 11) across labs, manufacturing, and serialization/track-and-trace systems.
- Oversee complaint handling, field alert/biological product deviation reporting, recall readiness, and post-market commitments for RLT.
- Lead quality due diligence and integration for M&A, licensing, and external manufacturing networks specific to radiopharmaceuticals and radioisotope supply.

Essential Requirements:

- Bachelor's degree required, advanced degree in a scientific discipline (Pharmacy, Chemistry, Chemical Engineering, Radio pharmacy, Nuclear Medicine, or related field) preferred.
- 12+ years of progressive Quality/GxP experience in pharmaceuticals or biologics, including 6+ years in radiopharmaceuticals or sterile/aseptic operations; RLT experience strongly preferred.
- Must have a working knowledge of FDA/EMA/ICH regulatory requirements
- Must have a broad cGMP experience with knowledge and understanding of manufacturing, quality control, and validation requirements and activities.

- Approximately 25% travel required.

Desirable Requirements:

- Prior accountability for batch release/Responsible Person or Qualified Person interface in EU or equivalent markets.
- Implementation of digital QMS, eQMS, and analytics-driven quality dashboards.
- Experience with novel radioisotopes (e.g., Lu-177, Ac-225) and associated supply chain constraints.
- Vendor/CMO oversight for radiolabeling, sterile fill-finish, and last-mile distribution.
- Post-approval change management and lifecycle management for radiopharmaceuticals.

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: 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.

Alternative Location 1
Barcelona Gran V í a, Spain

Alternative Location 2
Ljubljana, Slovenia

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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