Global Quality Platform Head RLT (remote)

Job ID
REQ-10034743
Dic 23, 2024
Estados Unidos

Resumen

At Advanced Accelerator Applications, a Novartis Company, we are committed to leading innovation in nuclear medicine and delivering the next generation of targeted radioligand therapy to cancer patients. We are looking for an experienced Quality Leader to help us reach our ambitious goals.

As the Global Quality Platform Head for Radioligand Therapies (RLT), you will be responsible for ensuring Quality oversight for the RLT platform and have ownership of budget, headcount and reporting lines. You will be a member of the Novartis Technical Operations Quality Leadership Team (TQLT) and the RLT Platform Leadership Team.

About the Role

Key responsibilities:

- Ensure implementation and maintenance of quality systems, policies and procedures within the Platform or with external suppliers as well as ensure oversight and control of external suppliers related to Active Pharmaceutical Ingredient, excipients and packaging materials and a timely escalation and effective communication in order to raise quality issues to the appropriate levels of management.
- Assure sites implement a coherent Quality governance structure, including a site quality review board, a defined escalation process and quality planning.
- Ensure readiness for regulatory inspections and assure sites / regions implement a coherent Quality governance structure, including a site quality review board, a defined escalation process and quality planning.
- Improve metrics and KPI analysis to drive quality performance and drive best practice sharing across the network. Support the implementation of new technologies and innovation including global solutions and new analytical technologies to support the Novartis Technical Operations (NTO) strategy.
- Assure sites / suppliers are improving their product performance understanding through knowledge management and continuous improvement (e.g. APR/PQR system and process capability) and drive improvement of quality standards through implementation of new Quality Modules, site quality risk assessments, regulatory compliance and quality system reviews.
- Serve as main point of contact for the wider Novartis network for queries relating to Platform Quality and ensure that the Quality culture at the sites is implemented (through the Site Quality Heads). Lead the Quality section of the Platform monthly management meeting.
- Support, advise and give guidance Site Quality Heads and Suppliers directly or through the Regional Heads in relation to GMP and regulatory matters and in issue resolution. Escalate significant cGMP or regulatory issues to the Global Head NTO Quality and represent the Platform at the NTO Quality Leadership Council (TQLC). Follow up with Platform sites to assure the timely closure of corrective

actions resulting from health authority inspections and corporate audits.
- Develop annual Site Quality Plans in cooperation with Network Sites based on inputs from Novartis and NTO Quality Plans and support product launches and PAI readiness at the Network sites.

Essential Requirements:

- Bachelor's degree Chemistry, Biology, Pharmacy, Biotechnology, Biomedical Engineering, or related degree.
- 15+ years' experience in Quality Control, Quality Assurance, Quality Systems, Quality / Regulatory Compliance, Operational GxP area(s) (Manufacturing / Development), Supplier Quality and / or Post Market Quality within the pharmaceutical industry including prior experience with aseptic manufacturing.
- 5+ years' experience leading and developing people including experience leading leaders in a global, matrix organization.
- Must have a working knowledge of FDA and ex-USA regulatory requirements as well as industry quality management tools, standard, and quality systems. Understanding of United States Pharmacopeia (USP), European Pharmacopeia (EP), American Chemical Society (ACS).
- In-depth knowledge of cGMP, applicable FDA Regulations (e.g., 21 CFR 4, 7, 11, 210, 211, 212), ICH Guidelines, EU Pharmaceutical Regulations and Directives, ISO Standards, etc.
- Prior experience with Health Authority Audits and Inspections.

Desirable Requirements:

- Prior experience in Radioligand Therapy is 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.

#Remote

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: novartis-life-handbook.pdf.

Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

The pay range for this position at commencement of employment is expected to be between $245,600 and $368,400 per year; however, while salary ranges are effective from 1/1/24 through 12/31/24 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 who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. 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. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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.

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