Site Quality Head, Indianapolis Isotopes Site

Job ID
REQ-10022669
Oct 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 professional to help us reach our ambitious goals.

As the Site Quality Head, you will be accountable for supporting site start up and Quality operations at our new Radioligand Therapy (RLT) Isotope Manufacturing site in Indianapolis. You'll provide quality assurance oversight and technical and strategic leadership for all quality-related matters.

About the Role

Key Responsibilities:

- Support site start up, expansions, and product transfers. Create and maintain updated project plans to track progress, and support in informing senior management. Ensure proper preparation and consolidation of the budget for the Quality Unit.
- Provide leadership for strategic site initiatives and represent site SLT quality in local cross-functional and global projects teams as team member or team leader that represent site quality.
- Provide leadership, direction and support to the people within the Quality department and ensure that they are qualified, achieve a high level of competence, are motivated and carry out their duties in a safe manner.
- Work with internal and external personnel to create user requirements and specifications to be used for projects in compliance with company standards for equipment, process and facilities.
- Ensure all facilities, utilities and equipment are designed and installed to be operated in a safe and effective manner and are compliant with applicable standards
- Ensure that during project phase planning, construction, commissioning, qualification (IQ, OQ and PQ) including any other validation activity complies with cGMP
- Timely escalation of risks in meeting timelines and / or budget incorporating site master planning and the long-term strategic plan.
- Ensure adequate management of product critical quality issues (deviations, out of specifications). Ensure investigations are correctly executed and adequate CAPAs are defined, and proper follow up of CAPAs effectiveness. Review, provide guidance for, escalate where appropriate, and approve Health Authority notifications (compliance related such as Exception requests, other).
- Define, implement, monitor, consolidate and analyse Site Quality KPIs. Ensure Site Quality Committee is established, ensure relevant corrective and preventive actions are endorsed and implemented.
- Drive for Site management team accountability. Coordinate the generation and monitor the execution of the Site Quality Plans, DI Plan, Site Quality Risk Assessments and other relevant gap assessments.

Essential Requirements:

- BS in Life Sciences and/or related experience in lieu of degree. 10 years of experience in GMP Pharmaceutical Manufacturing (including laboratory operations and Aseptic experience), and at least 3 years of relevant experience in Quality Control and/or Quality Assurance.
- Prior leadership experience, including experience working in a matrix organization. Highly developed management and communication skills.
- Demonstrated success managing inspections from major Health Authorities (e.g. US FDA, EMA). In-depth knowledge of cGMP, FDA regulations (21 CFR Parts 211, 212), and ICH regulations. Understanding of United States Pharmacopoeia (USP), European Pharmacopoeia (EP), American Chemical Society (ACS)
- Proven ability to manage multiple projects with moderate resource requirements, risk and/or complexity.
- Experience in process improvement approaches (Lean Six Sigma, Total Quality Management, 5S, etc.). Ability to define and implement productivity improvement measures.

#LI-On-site

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 $158,400.00 and $237,600.00 pr 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

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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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