Head, Site QA Operations

Job ID
REQ-10010438
Juil 03, 2024
Etats-Unis

Résumé

About this role: The Head, Site QA Operations will ensure compliance with all applicable GxP standards, regulations, guidelines, and guidance documents associated with Radioligand Therapy (RLT) pharmaceutical Production and Quality Control test-ing at the RLT Millburn site. The role is accountable for the quality oversight of Production, Quality Control testing and Quality Engineering/Validation supporting the RLT Millburn site, including final product disposition.

About the Role

Key Responsibilities:

- Lead and develop the Site Quality Assurance Operations Team (4-6 direct reports, 20-25 indirect reports), including, QA Shop Floor, QA Batch Release and QA Engineering.
- Act as Responsible Person for the final disposition of products. Ensure timely and compliant final product disposition of the Product.
- Lead resource allocation and capacity planning to ensure compliance to all applicable GxP requirements, adherence to Novartis standards, and delivery of projects / continuous quality improvement initiatives.
- Build and sustain a high-performing team through effective delegation and empowerment, talent development, and coaching and mentoring and as a leader of leaders, effectively develop and coach people managers.
- Lead cross functional groups and build collaborative interfaces with all stakeholders to ensure quality systems such as deviation management, investigations, corrective and preventive actions, change control and complaint management are in place and followed.
- Support commercial and clinical product FDA/Regulatory interactions for the RLT Millburn site activities and products to ensure successful regulatory submissions.
- Oversees the product release and deviation processes and support escalation management and all commercial product field actions with FDA.
- Ensure consistency of quality related processes and procedures. Leads or participates in Quality projects.
- Ensure preparation and delivery of relevant Validation Plans.
- Actively support audits/inspection management, including, front room.
- Develop and strengthen the Quality Culture within the Quality Unit and at Site level ensuring GMP compliance and continuous quality management improvement by facilitating and promoting empowerment and accountability.
- Ensure adequate management of product critical quality issues (deviations, out of specifications) and escalate issues / risks to site leadership, as needed.
- Participate to the preparation and consolidation of the budget of the Quality Unit.
- Ensure health & safety procedures are followed.

Essential Requirements:

- BSc in Chemistry, Biology, Pharmacy, Biochemistry, Engineering, or related experience. Advanced Degree is preferred.
- At least 10+ years' experience in Quality Assurance, Quality Control, Quality Systems, Compliance, Operational GxP area(s) (Manufacturing / Development) within the pharmaceutical, diagnostic and / or medical device industries. Experience in advanced therapies (CGT, RLT, etc) is preferred.
- Prior experience leading a Quality Assurance organization.
- Prior experience with aseptic pharamaceutical manufacturing.
- In-depth knowledge and understanding of cGMPs, aseptic pharmaceutical manufacturing, Quality Control and Quality Assurance, including, applicable regulations and standards.
- Understanding of United States Pharmacopeia (USP), European Pharmacopeia (EP), American Chemical Society (ACS).
- Direct experience with investigations and root cause analysis in pharmaceutical or medical device products.
- Experience reviewing manufacturing and QC validation documents.
- Experience developing high performing teams and talent management. Prior experience successfully leading Health Authority Audits / Inspections, including, front room / back room, readiness, strategy and response to findings / observations is highly preferred.
- Experience in process improvement approaches (e.g., Lean, Six Sigma, 5s) and leading projects is preferred.

The pay range for this position at commencement of employment is expected to be between $158,400 and $237,600 per year; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. 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.

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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.

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

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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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