Site QC Head (Associate Director)

Job ID
REQ-10029404
Dic 03, 2024
USA

Sommario

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 Control Leader with previous experience in pharmaceuticals, diagnostics and/or medical device to help us reach our ambitious goals.

As the Site QC Head, you will lead the Millburn Quality Control organization, including release and in-process testing, environmental monitoring and sterility assurance, stability testing, lab investigations, and analytical science and technology.

This role reports to the Millburn Site Quality Head.

About the Role

Key responsibilities:

- Lead the Millburn Site QC function, about 40 associates, and manage resource allocation to ensure timelines and key milestones are met. Develop and strengthen the Quality Culture within the Quality Control organization. Ensure associates have development plans and identify opportunities for growth.
- Ensure quality systems for Quality Control, Environmental Monitoring, Stability, Analytical Science and Technology meet all applicable Health Authority regulations, guidelines, etc.
- Set and manage department objectives and performance. Develop and monitor KPIs across the organization, including, cycle time, reliability, RFT, etc. Identify and lead continuous improvement activities.
- Evaluate impact and anticipate implications of important emerging regulatory requirements, industry trends and external regulatory actions associated with Quality Control, Environmental Monitoring, Stability, Analytical Science and Technology.
- Collaborate through effective relationships and partnership with External Relations for the ongoing monitoring of emerging regulations, and where appropriate, participate in / collaborate with external working groups.
- Develop and implement strategies, processes and plans for inspection readiness. Represent Quality Control during internal and external inspections.
- Ensure adequate management of QC related validations, transfers, investigations related activities (deviations, OOS, OOE, OOT, CAPAs, trending), and Change Controls.
- Procure site validation and qualification support, support site launches of manufacturing products. Ensure and maintain qualified status of lab equipment and methods for intended use in QC laboratories
- Participate in the preparation and consolidation of the Quality Control organization’s budget.

Essential Requirements:

- BSc in Chemistry, Biology, Pharmacy, Biotechnology, Biomedical Engineering, or related experience. Advanced Degree is preferred.
- 10+ 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, diagnostic and / or medical device industries including prior experience with aseptic manufacturing. Experience in advanced therapies (Cell and Gene Therapy, Radioligand Therapy, etc.) is preferred.
- 5+ years' experience leading and developing people. Experience developing high performing teams and talent management. Experience leading leaders is preferred.
- 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 / Inspections, including, front room and response to findings / observations.
- Must have an understanding of pharmaceutical industry trends and practices. Broad cGMP experience is required with knowledge and understanding of manufacturing, quality control, and validation requirements and activities.
- Prior / advanced experience within microbiology, environmental monitoring, sterility assurance is preferred.

Desirable Requirements:

- Prior experience in a global, matrix organization
- Experience in process improvement approaches (e.g., Lean, Six Sigma, 5s) and leading projects

#LI-Onsite

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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.

The pay range for this position at commencement of employment is expected to be between $ 151,200 and $226,800 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

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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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