Site Quality Head, Millburn

Job ID
REQ-10053935

6月 03, 2025

USA

摘要

#LI-Onsite
Location: Millburn, New Jersey

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 (RLT) to cancer patients. We are looking for an experienced pharmaceutical industry professional to lead the Quality function at our Millburn site.

As the Site Quality Head, you will provide quality assurance oversight and be accountable for Quality operations at the Millburn site. You will provide technical and strategic leadership for the Manufacturing site in all quality and cGMP compliance related matters. You will ensure that all aspects of the operational business comply with cGMP legal and regulatory requirements and Novartis Quality Manual requirements. You will also be part of the Site Senior Leadership Team.

About the Role

Key responsibilities:

- Provide leadership, direction and support to the people within the Quality Assurance department and ensure that they are qualified, achieve a high level of competence, are motivated and carry out their duties in a safe manner.
- Timely escalation of risks in meeting timelines and / or budget incorporating site master planning and the long-term strategic plan.
- 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. Establish Quality as a valued business partner.
- Define, implement, monitor, consolidate and analyze 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.
- Ensure proper preparation and consolidation of the budget for the Quality Unit.
- 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.

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), at least 3 years combined of relevant experience in Quality Control and/or Quality Assurance.

- Proven track record and practical experience in supporting a Quality Control operations unit and operating in full compliance with global cGMP requirements. Successfully managed 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. Highly developed management and communication skills, with experience in working in a matrix organization.

- Experience in process improvement approaches (Lean Six Sigma, Total Quality Management, 5S, etc.) Understands economic business impacts of decisions. Defining and implementing productivity improvement measures.

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.

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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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

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部门
Operations

Business Unit
Innovative Medicines

地点
USA

状态
New Jersey

站点
Millburn

Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Job ID
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Site Quality Head, Millburn

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