QC and AS&T Lead (Manager)

Job ID
REQ-10014855
Sep 03, 2024
USA

Summary

Location: Indianapolis, Indiana (on-site)

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 QC/AS&T professional with previous experience in a high-tech production environment to help us reach our ambitious goals.

As the QC and AS&T Lead, you will support the design, qualification, and validation of the QC laboratory at our new, state-of-the-art Lutetium Isotope manufacturing site. You will be the subject matter expert and single point of contact for all QC related activities to ensure efficient operation at site go-live. Once manufacturing has started, you will ensure that all quality control activities (both analytical chemistry and microbiology) comply with cGMP and good laboratory practices. Responsibilities also include the environmental monitoring program, calibration, maintenance of equipment and periodic method evaluation/re-qualification in the laboratory environment.

About the Role

Key Responsibilities:

- Ensure resources are in place to support the design, qualification, and validation of the QC laboratories. Define user requirement specifications for QC related equipment. Ensure that laboratory and QC equipment is calibrated/validated/qualified.
- Define the hiring strategy for operational readiness and set-up the future QC organization. Provide leadership to the Quality Control team. Determine training needs, provide training, and maintain training records. Review, update, and approve quality control related procedures and work instructions.
- Ensure the quality control lab and related activities meet cGMP, good laboratory practices and registered methods or monographs. Oversee accurate execution of the quality control activities for raw materials, intermediates and finished products and ensure timely execution to allow for on time product release.
- Responsible for defining and establishing the environmental control program and compilation of periodic review reports.
- Lead OOS/OOT/OOE investigations and define appropriate corrective and preventive actions.
- Define improvements and lead projects to improve efficiency and compliance of the QC laboratory. Ensure that digital solutions are integrated in laboratory processes.
- Perform periodic method reviews, define improvement, and ensure that source documentation for regulatory submission is drafted, reviewed, and approved.

- Responsible to manage the QC operational budget. Drive QC related Capex.

Essential Requirements:

- Bachelor’s degree in chemistry, pharmacy or food technology or equivalent scientific education and 4 years of experience in senior QC roles in a high-tech production environment.
- Excellent knowledge of good laboratory practices and cGMP.
- Outstanding leadership and coaching skills. Open and clear collaboration and communication with team and with all stakeholders.
- Open to new technologies and continuous improvement behavior. Quick to adapt new technology and techniques to eliminate non-value adding activities and improve productivity / performance through new processes.

Desirable Requirements:

- Advanced degree
- Prior experience with radiation safety requirements

The pay range for this position at commencement of employment is expected to be between $118,400 and $177,600 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.

Benefits and rewards: Read our handbook to learn about all the ways we’ll help you thrive personally and professionally: Thrive Together (novartis.com).

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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