Senior Quality Assurance Engineer Lead

Job ID
REQ-10019304
Aug. 19, 2024
USA

Zusammenfassung

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 with validation, maintenance, engineering or quality experience to join the team at our new Lutetium isotope manufacturing site in Indianapolis. As the Senior Quality Assurance Engineer Lead, your main focus will be providing support to the QA Operations organization for the review and approval of technical QA records. Initially the focus will be support for the design, construction, commissioning, qualification and validation of the new facility. Once the site has been qualified and approved, you will act as the main contact for technical QA related support for the site including acting as SME for change controls, reviewing technical QA documents, supporting deviation investigations and CAPA's from a quality perspective, etc. In this second phase, you will also be a key player for future site expansions.

About the Role

Major accountabilities:

First phase: Greenfield project for the construction, qualification and validation of the lutetium isotope manufacturing site

- Acts as QA contact point and subject matter expert for the design, construction, commissioning, qualification and validation activities for manufacturing and QC areas
- Represents the quality function in cross-functional project teams and in commissioning activities such as FAT and SAT
- In collaboration with the Site's Manufacturing Science and Technology department (MS&T) reviews and approves the establishment, review and approval of the expansion project qualification and validation master plans
- Acts as a subject matter expert and point of contact for the inclusion of Novartis and regulatory requirements into the commissioning, qualification and validation master plans and protocols
- Supports the creation and review of source documentation intended to be used for regulatory submission. Supports the preparation and execution of pre-approval inspection by FDA or any other health authority

Second phase: Commercial manufacturing

- Supports further expansion of the site with additional manufacturing lines including establishment, review

and approval of maintenance and calibration strategy, validation and maintenance protocols, reports and records for the production, warehouse/supply chain and QC departments

- Acts as single point of contact for QA validation/calibration and maintenance during audits and inspections. Primary subject matter expert for GMP regulatory inspections, specifically for qualification. Performs QA oversight for validation and qualification activities for specific manufacturing and QC studies
- Acts as QA investigator to review deviations or OOx related to validation, maintenance, calibration, and technical production related issues. Ensures the root cause is determined, evaluates the impact on product quality and disposition of the batches. Defines corrective and preventive actions linked to the records in scope of the functions and ensures timely implementation
- Reviews and approves changes related to the facility, computerized systems and production/QC equipment. Supports the GAP assessments between the site's practices/local procedures and Corporate procedures. Acts as main contact for the inclusion of new validation/maintenance/calibration/engineering Corporate/Global procedures in Novartis RLT Indianapolis isotope manufacturing 's quality systems documentation system.
- Contributes to the generation of the Annual product review

Essential Requirements:

- Bachelor's degree in a scientific area. Advanced degree preferred.
- 5 years of experience in validation, maintenance, engineering or technical quality in a pharmaceutical cGMP or medical device environment
- Knowledge of cGMP for the defined area
- Open and clear collaboration and communication skills
- Very good administrative skills and working knowledge of MS365 and Adobe Acrobat

The pay range for this position at commencement of employment is expected to be between $112,800 and $169,200 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.

#LI-Onsite

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

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

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.

Abteilung
Operations
Business Unit
Innovative Medicines
Ort
USA
Website
Indianapolis
Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

Apply to Job

iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } }

Job ID

REQ-10019304

Senior Quality Assurance Engineer Lead

Apply to Job

Source URL: *https://www.adacap.com/careers/career-search/job/details/req-10019304-senior-quality-assurance-engineer-lead*

List of links present in page

1. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://talentnetwork.novartis.com/network
4. https://www.novartis.com/careers/benefits-rewards
5. mailto:us.reasonableaccommodations@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Indianapolis/Senior-Quality-Assurance-Engineer-Lead_REQ-10019304-1
7. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Indianapolis/Senior-Quality-Assurance-Engineer-Lead_REQ-10019304-1